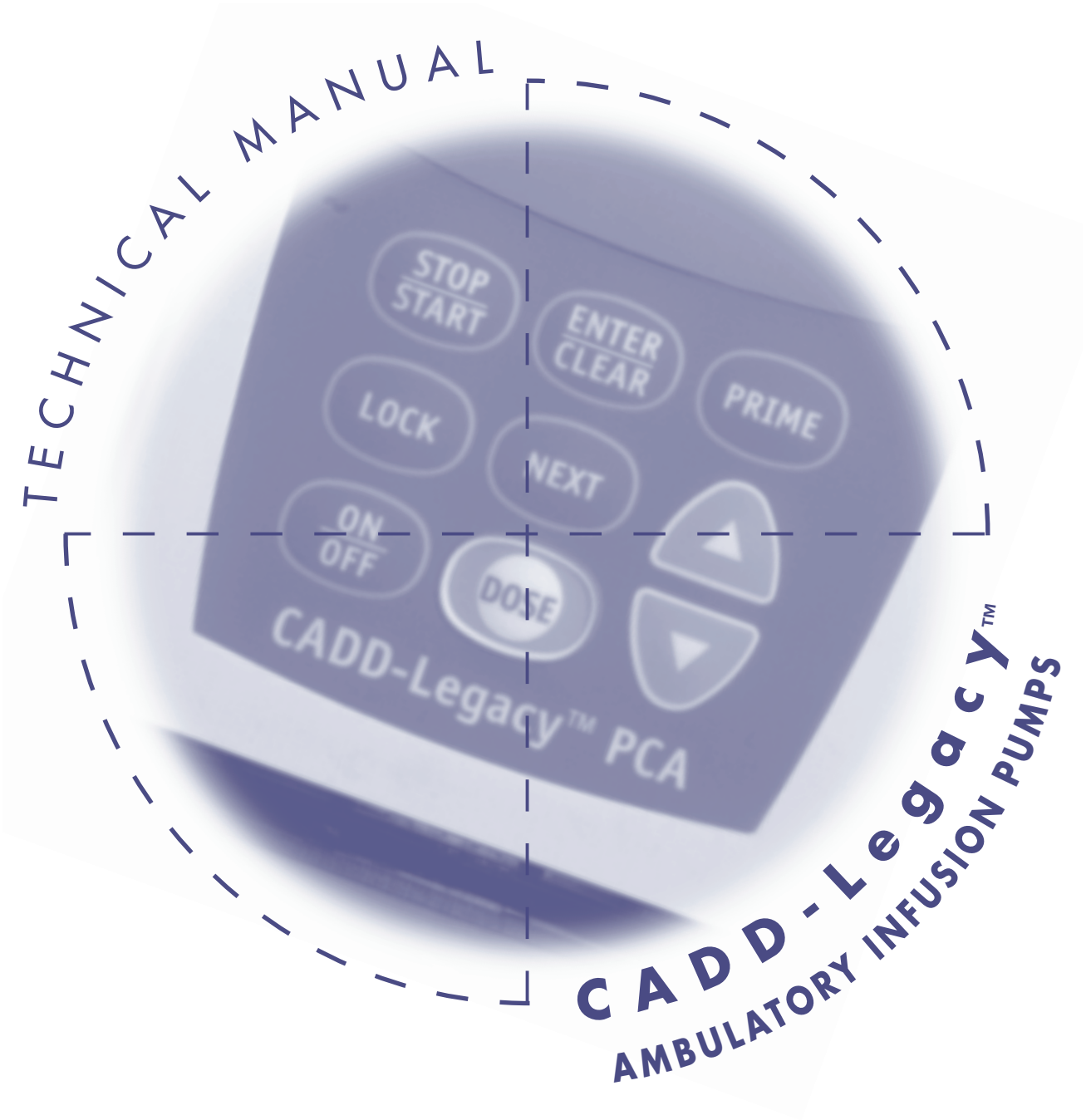
TECHNICAL MANUAL



CADD-Legacy™
AMBULATORY INFUSION PUMPS

CADD-Legacy™ 1 Pump
CADD-Legacy™ PCA Pump
CADD-Legacy™ PLUS Pump

Deltec

SIMS SMITHS INDUSTRIES
Medical Systems

For detailed instructions, specifications, warnings, warranties, and additional information on operating CADD® pumps, please refer to the *Operator's Manual* supplied with the product. If you have additional comments or questions concerning the operation of CADD® pumps, please call this number: **800-426-2448**. Our staff is available to help you twenty-four hours a day with the programming and operation of CADD® pump infusion systems.

The issue date of this Technical Manual is included on the back cover for the user's information. In the event one year has elapsed between the issue date and product use, the user should contact SIMS Deltec, Inc. to see if a later revision of this manual is available.

Issue Date: January 2000

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1 Introduction

This Technical Manual is intended to provide an understanding of the mechanical and electrical operation of the CADD-Legacy™ PCA, CADD-Legacy™ 1, and CADD-Legacy™ PLUS Computerized Ambulatory Drug Delivery pumps to persons familiar with these devices. The CADD-Legacy™ PCA, CADD-Legacy™ 1, and CADD-Legacy™ PLUS pump *Operator's Manuals* should be used in conjunction with this publication for complete information.

This manual also outlines cleaning and functional testing procedures that can be performed on the CADD-Legacy™ PCA, CADD-Legacy™ 1, and CADD-Legacy™ PLUS pumps.

WARNING:

This Technical Manual must be used by Biomedical Technicians only. Do not permit patients to have access to this manual. Do not disclose to the patient the pump's security codes or any other infomation that would allow the patient complete access to all programming and operating functions. Improper programming could result in death or serious injury to the patient.

IMPORTANT NOTICE:

CADD-Legacy™ PCA, CADD-Legacy™ 1, and CADD-Legacy™ PLUS pump operations and safety features are based on a microcomputer design. Inadequate servicing or tampering with the safety features of the pumps may seriously affect performance and safety.

For that reason, **ALL SERVICING AND REPAIR OF THE CADD-Legacy™ PUMPS MUST BE PERFORMED BY DELTEC OR ITS AUTHORIZED AGENTS.**

The manufacturer's warranty agreement shall become null and void if the pump is not used in accordance with the *Operator's Manual* and *Instructions for Use* for the pump accessories; or, the pump is serviced by persons other than Deltec or those authorized by Deltec.

Limited Warranty

The limited warranty associated with the CADD-Legacy™ PCA, CADD-Legacy™ 1, and CADD-Legacy™ PLUS pumps can be found in the product literature supplied with the product when originally purchased, which is incorporated herein by reference. DELTEC SPECIFICALLY DISCLAIMS ANY OTHER WARRANTY, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR USE. Deltec further disclaims responsibility for the suitability of the system for a particular medical treatment or for any medical complications resulting from the use of the system. The manufacturer shall not be responsible for any incidental damages or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the system.

If you wish to receive additional information about the extent of the warranty on these products, please contact your Deltec representative or call Customer Service at 1-800-426-2448.

All recommendations, information, and literature supplied by Deltec with respect to the CADD® product line are believed to be accurate and reliable, but do not constitute warranties. No agent, representative, or employee of Deltec has authority to bind Deltec to any representation or warranty, expressed or implied.

Exposure to Radiation, Ultrasound or Magnetic Resonance Imaging (MRI), or use near ECG equipment

CAUTION:

- **Do not expose the pump to therapeutic levels of ionizing radiation as permanent damage to the pump's electronic circuitry may occur. The best procedure to follow is to remove the pump from the patient during therapeutic radiation sessions. If the pump must remain in the vicinity during a therapy session, it should be shielded, and its ability to function properly should be confirmed following treatment.**
- **Do not expose the pump directly to ultrasound, as permanent damage to the pump's electronic circuitry may occur.**
- **Do not use the pump in the vicinity of magnetic resonance imaging (MRI) equipment as magnetic fields may adversely affect the operation of the pump. Remove the pump from the patient during MRI procedures and keep it at a safe distance from magnetic energy.**
- **Do not use the pump near ECG equipment as the pump may interfere with the operation of the equipment. Monitor ECG equipment carefully when using this pump.**

2 CADD-Legacy™ Pump

Delivery Modes

The CADD-Legacy™ ambulatory drug delivery pump provides measured drug therapy to patients in hospital or outpatient settings. The CADD-Legacy™ pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural space, or subarachnoid space infusion.

Epidural administration is limited to use with indwelling catheters for short term delivery of anesthetics and short or long term delivery of analgesics. Subarachnoid administration is limited to use with indwelling catheters for short-term delivery of analgesics.

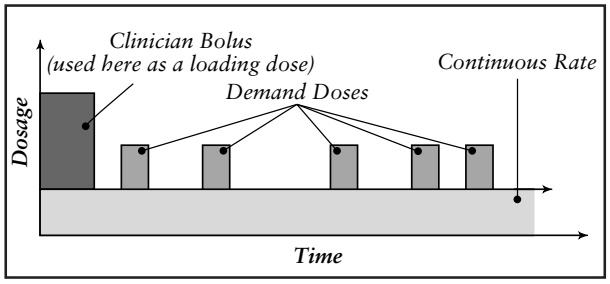

Figure 1. PCA mode delivery profile.

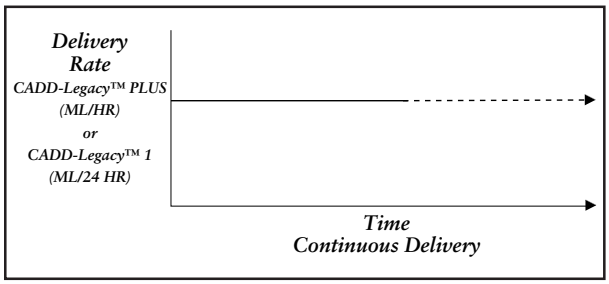

Figure 2. Continuous mode delivery profile.

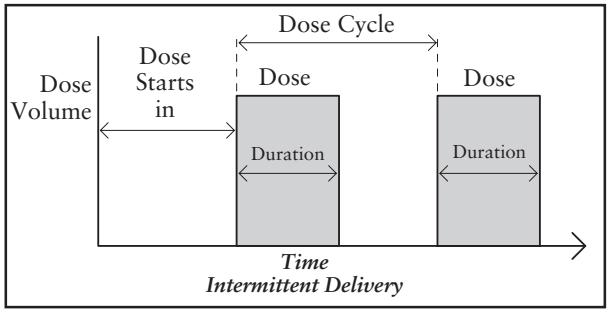

Figure 3. Intermittent mode delivery profile.

The CADD-Legacy™ PCA pump may be programmed to deliver medication in one of three ways: 1) continuous rate only, 2) patient-activated dose only and 3) continuous rate and patient-activated dose. (See figure 1.)

The CADD-Legacy™ PLUS pump may be programmed to deliver in one of two modes: (1) Continuous, (2) Intermittent . (See figures 2 and 3.)

The CADD-Legacy™ 1 pump operates in continuous mode. (See figure 2.)

Figure 4 shows a diagram of the CADD-Legacy™ pump.

PCA Delivery Profile

The PCA (patient-controlled analgesia) delivery mode is used for therapies that require a continuous rate of infusion, patient-controlled demand doses, or both, such as patient-controlled analgesia.

Continuous Mode Delivery Profile

The Continuous delivery mode allows the infusion of drug at a constant, programmed rate.

Intermittent Mode Delivery Profile

The Intermittent delivery mode allows the infusion of a specific volume of drug at regular programmed intervals.

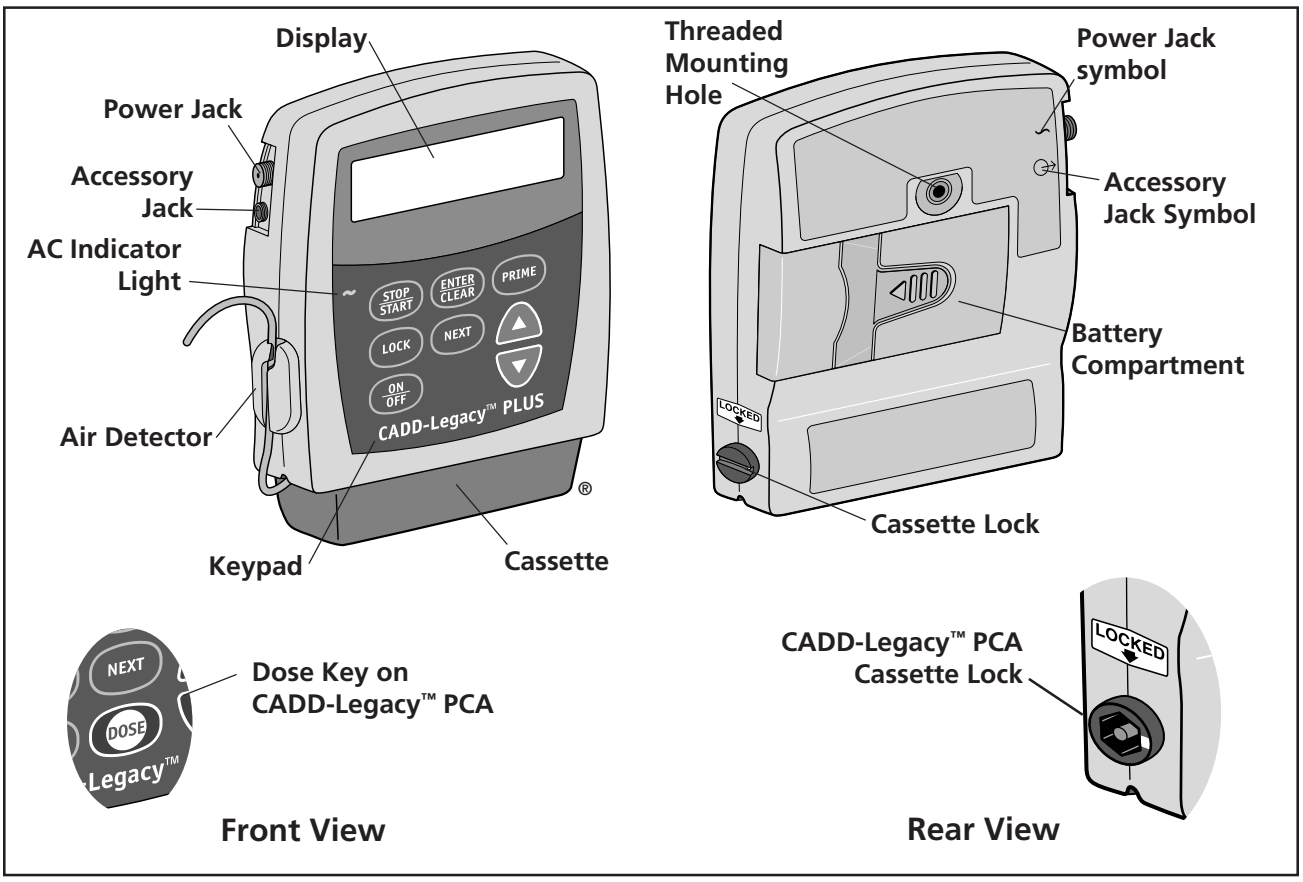

Figure 4. Front and Rear views of the CADD-Legacy™ Pump. Features are identical on all CADD-Legacy™ pumps except as illustrated for the CADD-Legacy™ PCA pump.

PCA Delivery Mode Scroll Ranges

Units	Starting	Increment		Maximum
ML	0.10	All values:	0.10	50.00
MG	10% of Concentration	Values between 0.01 and 0.5: Values between 0.50 and 100.0: Values between 100.0 and 1000.0: Values greater than 1000.0:	0.01 0.10 1.00 10.0	Concentration x 50
MCG	10% of Concentration	Values between 0.1 and 100: Values between 100 and 1000: Values greater than 1000:	0.10 1.00 10.00	Concentration x 50

Table 1. PCA delivery mode: continuous rate scroll ranges.

	Milligrams			
Concentration	Demand Dose		Clinician Bolus	
mg/ml	increment	max.	increment	max.
0.1	0.01	0.99	0.01	2
0.2	0.02	1.98	0.02	4
0.3	0.03	2.97	0.03	6
0.4	0.04	3.96	0.04	8
0.5	0.05	4.95	0.05	10
1	0.05	9.9	0.05	20
2	0.10	19.8	0.10	40
3	0.15	29.7	0.15	60
4	0.20	39.6	0.20	80
5	0.25	49.5	0.25	100
10	0.50	99.0	0.50	200
15	0.75	148.5	0.75	300
20	1.00	198.0	1.00	400
25	1.25	247.5	1.25	500
30	1.50	297.0	1.50	600
35	1.75	346.5	1.75	700
40	2.00	396.0	2.00	800
45	2.25	445.5	2.25	900
50	2.50	495.0	2.50	1000
55	2.75	544.5	2.75	1100
60	3.00	594.0	3.00	1200
65	3.25	643.5	3.25	1300
70	3.50	693.0	3.50	1400
75	3.75	742.5	3.75	1500
80	4.00	792.0	4.00	1600
85	4.25	841.5	4.25	1700
90	4.50	891.0	4.50	1800
95	4.75	940.5	4.75	1900
100	5.00	990.0	5.00	2000

Table 2. Demand dose, clinician bolus scroll ranges, milligrams

	Micrograms			
Concentration	Demand Dose		Clinician Bolus	
mcg/ml	increment	max.	increment	max.
1	0.05	9.9	0.05	20
2	0.10	19.8	0.10	40
3	0.15	29.7	0.15	60
4	0.20	39.6	0.20	80
5	0.25	49.5	0.25	100
10	0.50	99.0	0.50	200
15	0.75	148.5	0.75	300
20	1.00	198.0	1.00	400
25	1.25	247.5	1.25	500
30	1.50	297.0	1.50	600
35	1.75	346.5	1.75	700
40	2.00	396.0	2.00	800
45	2.25	445.5	2.25	900
50	2.50	495.0	2.50	1000
55	2.75	544.5	2.75	1100
60	3.00	594.0	3.00	1200
65	3.25	643.5	3.25	1300
70	3.50	693.0	3.50	1400
75	3.75	742.5	3.75	1500
80	4.00	792.0	4.00	1600
85	4.25	841.5	4.25	1700
90	4.50	891.0	4.50	1800
95	4.75	940.5	4.75	1900
100	5.00	990.0	5.00	2000
200	10.00	1980.0	10.00	4000
300	15.00	2970.0	15.00	6000
400	20.00	3960.0	20.00	8000
500	25.00	4950.0	25.00	10000

Table 3. Demand dose, clinician bolus scroll ranges, micrograms

	Milliliters		
Demand Dose		Clinician Bolus	
increment	max.	increment	max.
0.05	9.9	0.05	20

Table 4. Demand dose, clinician bolus scroll ranges, milliliters

Specifications (Nominal)

General Pump Specifications

Resolution
Medication Cassette™ Reservoir or CADD® Administration Set, 0.050 ml/pump stroke nominal

Size
4.1 cm x 9.5 cm x 11.2 cm (1.6 in. x 3.8 in. x 4.4 in.) excluding cassette or other accessories

Weight
391 g (13.8 oz.) including 2 AA batteries, empty 100-ml Medication Cassette™ Reservoir, and air detector, excluding other accessories

Pump Alarms
Low battery power; depleted battery power; battery dislodged; pump stopped; pump fault; low reservoir volume; high delivery pressure; air in line; disposable not attached when run attempted; motor locked; upstream occlusion; reservoir volume empty; program incomplete; remote dose cord removed; key stuck; disposable detached, power removed, value not saved.

Bolus Volume at Occlusion Alarm Pressure
0.050 ml resolution sets/reservoirs:
< 0.15 ml

Power Sources
Two AA alkaline batteries such as DURACELL® or EVEREADY Energizer®; AC adapter.

An internal battery powers the clock. When it is depleted, it cannot reliably maintain the clock time. This battery must be replaced by SIMS Deltec, Inc. The internal battery has an expected life of 5 years.

System Operating Temperature*
+2°C to 40°C (35°F to 104°F)

System Storage Temperature*
-20°C to 60°C (-4°F to 140°F)

System Delivery Accuracy*
± 6% (nominal)

High Pressure Alarm
26 (±14) psi, 1.79 (± 0.97) bar

Air Detector Alarm
Single bubble
Low sensitivity = greater than 0.250 ml
High sensitivity = greater than 0.100 ml
Multi-bubble = 1.0 ml nominal

Delivery Mode Specifications

CADD-Legacy™ PCA pump

Reservoir Volume
1 to 9999 or Not In Use; programmable in 1 ml increments, displayed in 0.1 ml increments
Default: 1 ml

Units
Milliliters (ml), milligrams (mg), micrograms (mcg)
Default: milligrams

Concentration
Mg/ml: 0.1, 0.2, 0.3, 0.4, 0.5, 1, 2, 3, 4, 5, 10, 15, ... 95, 100 (Default: 100 mg/ml)
Mcg/ml: 1, 2, 3, 4, 5, 10, 15, ...95, 100, 200, 300, 400, 500 (Default: 500 mcg/ml)

Continuous Rate
0 to 50 ml/hr (or the mg or mcg equivalent)
(See Table 1 for scroll ranges)

Demand Dose
0 to 9.9 ml in 0.05 ml increments (or the mg or mcg equivalent)
(See Tables 2 and 3 for scroll ranges)
Delivery rate (Continuous Rate + Demand Dose): 125 ml/hr nominal

Dose Lockout
5 minutes to 24 hours in the following increments:
1 minute for values between 5 and 20 minutes
5 minutes between 20 minutes and 24 hours
Default: 24 hours

Doses Per Hour
1 to 12 doses in 1 dose increments (will also be limited by the Demand Dose Lockout value)
Default: 1 dose/hr

*System is defined as a CADD-Legacy™ pump with an attached Medication Cassette™ Reservoir and CADD® Extension Set with integral anti-siphon valve, or an attached CADD® Administration Set with integral or add-on anti-siphon valve.

Doses Given
0 to 999

Doses Attempted
0 to 999

Given
0 to 99999.95 in 0.05 unit increments or
0 to 99999.99 in 0.01 unit increments
(increments converted to current units based on concentration)

Clinician Bolus
0.05 ml to 20.00 ml (or mg or mcg equivalent) (See Tables 1, 2 and 3 for scroll ranges)
Delivery rate (Continuous Rate + Clinician Bolus): 125 ml/hr nominal

CADD-Legacy™ 1 pump

Continuous Delivery Mode Specifications

Reservoir Volume
1 to 9999 or Not In Use; programmable in 1 ml increments, displayed in 0.1 ml increments
Default: 1 ml

Continuous Rate
1 to 3000 ml/24 hr in increments of 1 ml/24hr
Default: 0 ml/24hr

Given
0 to 99999.95 in 0.05 ml increments

CADD-Legacy™ PLUS pump

Intermittent Delivery Mode Specifications

Reservoir Volume
1 to 9999 or Not In Use; programmable in 1 ml increments, displayed in 0.1 ml increments
Default: 1 ml

Dose Volume
0.1 to 1000.0 ml in increments of 0.1
Default: 0.0 ml

Dose Duration
1 minute to 24 hours in the following increments:
1 minute from 00:01 to 00:10
5 minutes from 00:10 to 24:00
Default: 30 minutes

Dose Cycle
10 minutes to 96 hours in 5 minute increments
Default: 4 hours

KVO Rate
0 to 125.0 ml/hr in increments of 0.1 ml/hr
Default: 0 ml/hr

Dose Starts in
Immediate or 1 minute to 96 hours in the following increments:
00:01 from 00:00 to 00:10
00:05 from 00:10 to 96:00
Default: Immediate

Continuous Delivery Mode Specifications

Reservoir Volume
1 to 9999 or Not In Use; programmable in 1 ml increments, displayed in 0.1 ml increments
Default: 1 ml

Continuous Rate
0.1 ml/hr to 125.0 ml/hr in increments of 0.1 ml/hr
Default: 0.0 ml/hr

Given
0 to 99999.95 in 0.05 ml increments

Biomed Functions Specifications

Air Detector Status:
Off
On- low
On- high
Default: On-high

Upstream Occlusion Status:
Off
On
Default: On

Delivery Mode (CADD-Legacy™ PLUS only):
Continuous
Intermittent
Default: Intermittent

Compatible Medication Cassette™ Reservoirs and CADD® Administration Sets

- 50-ml or 100-ml Medication Cassette™ Reservoir, used with the CADD® Extension Set with Anti-siphon Valve.
- CADD® Administration Set with integral anti-siphon valve, with or without bag spike (allows use of flexible plastic bag or sterile vial with injector)
- CADD® Administration Set with add-on anti-siphon valve and bag spike (allows for gravity priming before attaching the add on anti-siphon valve)

Remote Dose Cord

Deltec provides a Remote Dose Cord for the CADD-Legacy™ PCA pump which is an extension of the DOSE key. The push button is a Single Pole Double Throw (SPDT) switch which operates in the same manner as the DOSE key. When the Remote Dose Cord is attached to the pump, the patient may press either the Remote Dose button or the DOSE key to receive a Demand Dose. The clinician may also use either the Remote Dose button or the DOSE key to deliver a clinician-activated bolus. For easy access, the Remote Dose Cord may be fastened to the patient's clothing or bedsheet with the attached clip.

There is an alarm/function present in the CADD-Legacy™ PCA pump. If the Remote Dose Cord is removed, the display shows a message "Remote Dose Removed". The pump sounds an audible alarm until the NEXT key is pressed to acknowledge the alarm.

NOTE:

To detach the Remote Dose Cord from the pump, grasp the Remote Dose Cord connector and pull back using a straight, steady motion.

3 Batteries

Battery Compatibility

Recommended Batteries

Two AA alkaline batteries are recommended for use in the CADD-Legacy™ pumps. Carbon-zinc, mercury, nickel-cadmium, nickel-metal-hydride, or zinc-air AA batteries should not be used.

Battery Life

The CADD-Legacy™ pumps have been designed to provide optimal battery life. The expected battery life in the CADD-Legacy™ pumps depends on the following factors:

- Programmed delivery rate
- Operating temperatures
- Battery type and brand
- Battery age

DURACELL® Alkaline Battery Life

Battery life is shortened significantly at very low operating temperatures. For example, at 0°C (32°F), an alkaline battery will yield approximately 30% of its normal capacity.

Alkaline batteries do not need to be stored in a refrigerator. After four years of storage at 21°C (70°F), an alkaline battery retains approximately 86% of its original capacity. Battery life will be shorter if the battery is stored above room temperature. An alkaline battery stored at 43°C (110°F) will be down to approximately 80% of its capacity within one year.

Recommended storage conditions are 10°C to 25°C (50°F to 77°F) with no more than 65% relative humidity noncondensing.

The following table may be used to predict typical alkaline battery life at different delivery rates when alkaline batteries are used in the CADD-Legacy™ pump. As expected, battery life decreases as the delivery rate increases. This table is based on laboratory tests using fresh DURACELL® alkaline batteries in CADD-Legacy™ pumps while the pumps were operating at room temperature.

Actual battery life may be significantly shorter depending on the operating temperature and the storage conditions of the battery.

Continuous Delivery Battery Life with Alkaline Batteries

Rate	Life	Volume
0.4 ml/hr	338 hrs	135 ml
4 ml/hr	178 hrs	712 ml
10 ml/hr	112 hrs	1120 ml
15 ml/hr	96 hrs	1440 ml
30 ml/hr	53 hrs	1590 ml
75 ml/hr	18 hrs	1350 ml
125 ml/hr	15 hrs	1875 ml

Table 5. Two AA Alkaline-type batteries used with the CADD-Legacy™ pumps.

Intermittent Delivery Battery Life with Alkaline Batteries

Dose Volume	Duration	Dose Cycle	KVO	Life	Volume
23.5 ml	1:00 hr	5:00 hr	0.2 ml/hr	193 hr	915 ml
61 ml	1:00 hr	6:00 hr	0.2 ml/hr	120 hr	1224 ml
125 ml	1:00 hr	6:00 hr	0.2 ml/hr	65 hr	1356 ml

Table 6. Two AA Alkaline-type batteries used with the CADD-Legacy™ pumps.

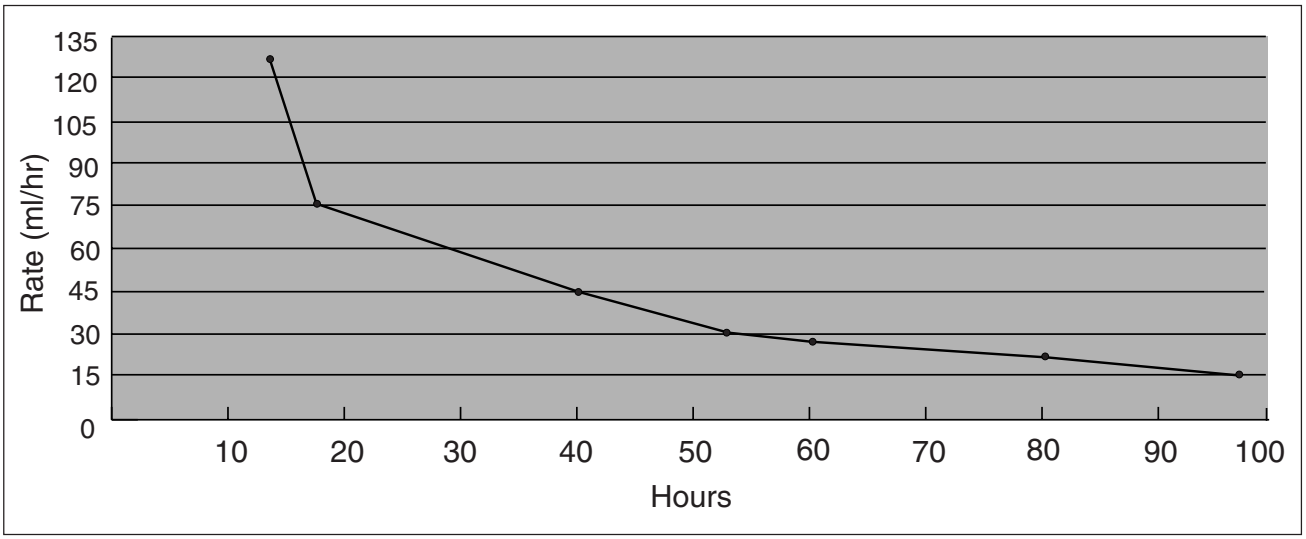

Figure 5. Operating time to low battery alarm using alkaline batteries.

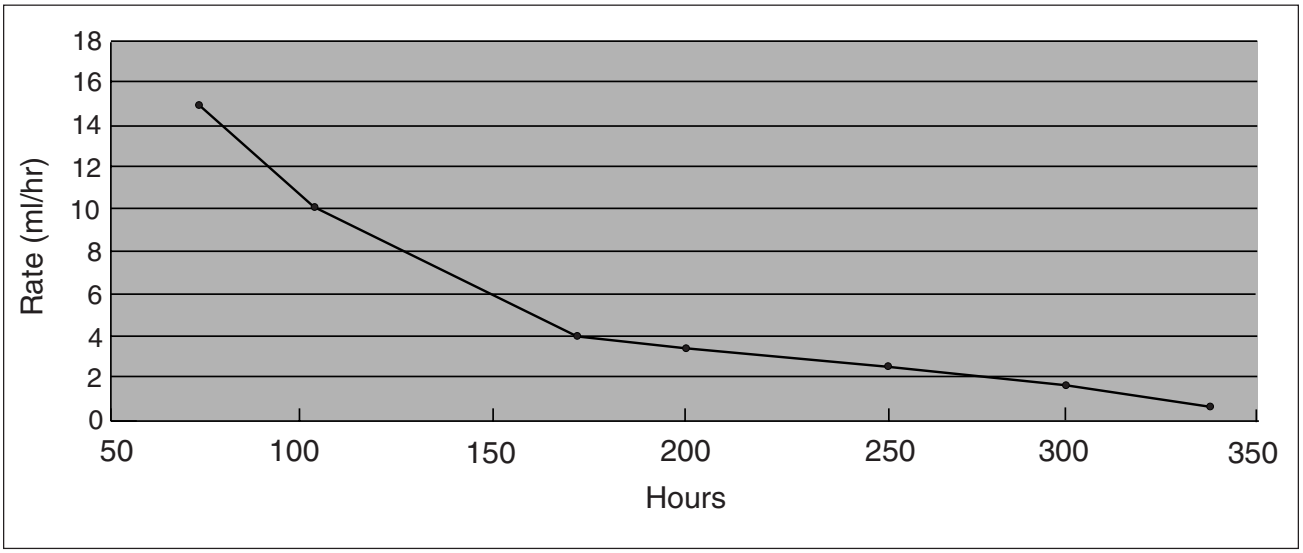

Figure 6. Operating time to low battery alarm using alkaline batteries.

Continuous Delivery Battery Life with Lithium Batteries

Rate	Life	Volume
0.4 ml/hr	413 hrs	165 ml
4 ml/hr	307 hrs	1228 ml
10 ml/hr	190 hrs	1900 ml
15 ml/hr	163 hrs	2445 ml
30 ml/hr	90 hrs	2700 ml
75 ml/hr	33 hrs	2475 ml
125 ml/hr	22 hrs	2750 ml

Table 7. Two AA Lithium-type batteries used with the CADD-Legacy™ pumps.

Intermittent Delivery Battery Life with Lithium Batteries

Dose Volume	Duration	Dose Cycle	KVO	Life	Volume
23.5 ml	1:00 hr	5:00 hr	0.2 ml/hr	300 hrs	1458 ml
61 ml	1:00 hr	6:00 hr	0.2 ml/hr	185 hrs	1911 ml
125 ml	1:00 hr	6:00 hr	0.2 ml/hr	125 hrs	2625 ml

Table 8. Two AA Lithium-type batteries used with the CADD-Legacy™ pumps.

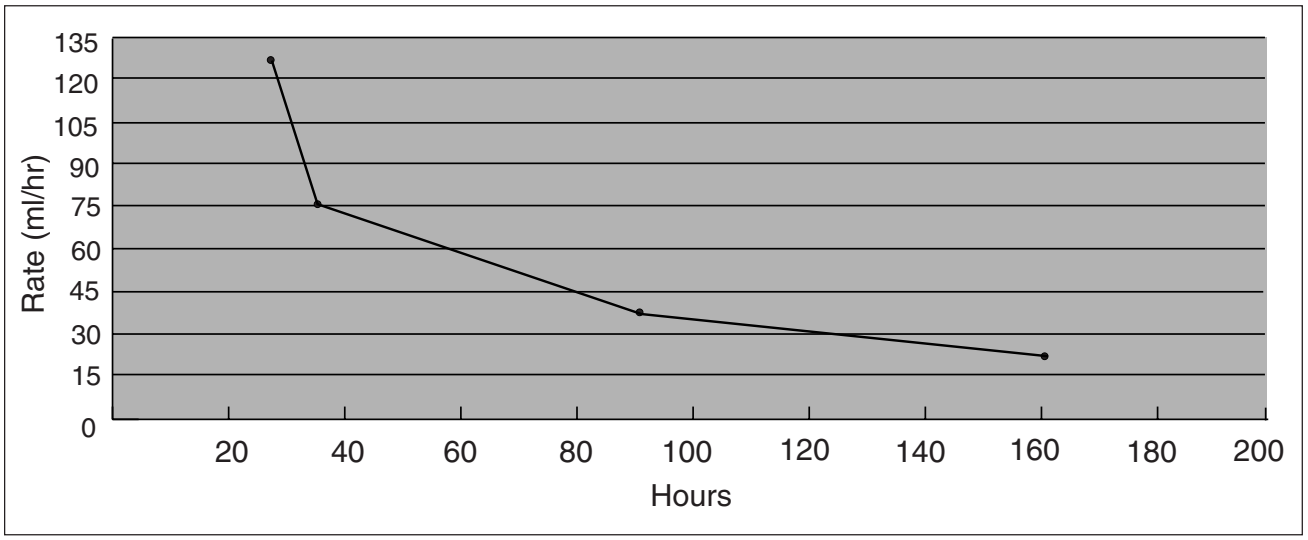

Figure 7. Dual-stroke operating time on lithium batteries.

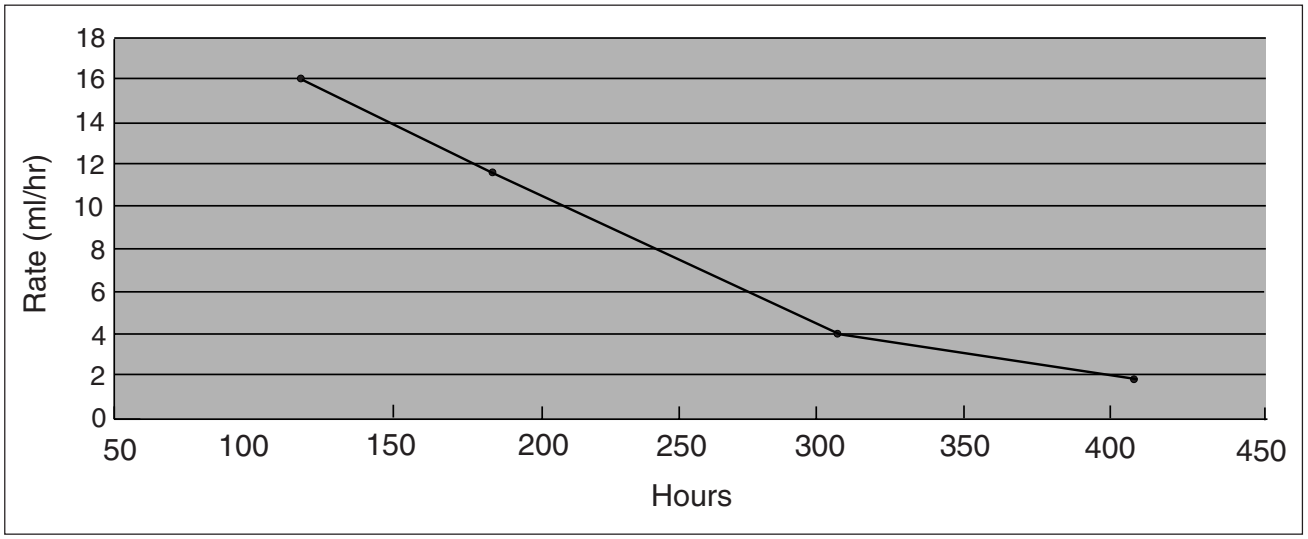

Figure 8. Single-stroke operating time on lithium batteries.

4 Construction

The pump's housing is made of a special high impact plastic. It is composed of two sections: the rear and front housing. The pump housing is sealed to ensure that the pump is water resistant. The battery compartment is not water resistant.

NOTE:

The CADD-Legacy™ ambulatory infusion pump is water resistant, but not waterproof. The pump is "Splashproof" and is characterized by the IEC code of IPX4.

The battery compartment is accessed through a removable door on the rear housing. Within the battery compartment is space for the batteries and the four battery contacts.

On CADD-Legacy™ pumps the Medication Cassette™ Reservoir or the administration set is attached to the bottom of the pump by inserting the two hooks on the cassette into the mating hinge pins on the pump. The pump and the reservoir or the administration set are then placed in an upright position on a firm, flat surface. The reservoir or the administration set must be secured in place by inserting a coin (or key if using the CADD-Legacy™ PCA pump) in the slot on the pump's locking button, pushing the button in and turning the button one-quarter turn counter-clockwise.

NOTE:

The Medication Cassette™ Reservoir and the administration set are intended for single use only.

The keyboard, located on the front housing, is composed of eight membrane switches (nine membrane switches on the CADD-Legacy™ PCA pump) and is sealed against moisture. All of the keys contain domes to provide a tactile feel when the key is pressed. The keyboard keys are sensed by the pump's microprocessor.

The Liquid Crystal Display (LCD), also located on the front housing, shows the pump status and programmed settings. The dot matrix display consists of 16 character columns with 2 rows of characters, and is selected by the pump's microprocessor according to status conditions and keyboard entries.

The microprocessor and other circuitry which control the pump are located on a printed circuit board. The board contains the Central Processing Unit (CPU), motor driver circuitry, and other circuitry. The circuitry is designed to reduce susceptibility to interference from electromagnetic fields and to dissipate electro-static discharge.

The LCD controller is mounted on the LCD using chip on glass technology.

The pumping mechanism subassembly contains the motor, gear train, camshaft, valves, expul-sor, sensing disk, infrared light source, infrared detector, occlusion sensors, disposable sensor, and cassette locking button. Via the motor driver circuitry, the pump's microprocessor controls motor rotation.

Two external port connectors are utilized for remote dose and external power input. The accessory jack is used for attachment of the Remote Dose Cord (CADD-Legacy™ PCA pump only) and interface cable. The Remote Dose Cord enables the patient to use either of two options to begin a Demand Dose when using the PCA delivery mode: (1) the Remote Dose button; or (2) the DOSE key.

The second port allows connection to an AC adapter.

The keyboard is connected to the printed circuit board via a flex circuit tail. Discrete wires connect the pumping mechanism, motor, and sensors to the printed circuit board.

The accessory jack in conjunction with the interface cable allows download of events using the CADD-DIPLOMAT™ software.

5 Theory of Operation

Keyboard Circuitry

The CADD-Legacy™ pumps are controlled by a microprocessor. The actions of the microprocessor are controlled by a program, which is contained in the memory.

Commands are issued to the microprocessor from the user via the eight keys on the keyboard (nine keys and Remote Dose Cord on CADD-Legacy™ PCA pump). The keys on the keyboard are arranged in a 3x3 matrix which feeds into the keyboard encoder. A key closure applies a ground to the associated input of the keyboard encoder. Key debounce circuitry resident in the keyboard encoder provides a clean output signal to the microprocessor for the duration of the key closure. The microprocessor reads keyboard status by accessing special memory locations in the keyboard encoder.

The Remote Dose Cord button (CADD-Legacy™ PCA pump only) consists of an SPDT switch with one switch output going to the microprocessor and the other going to the keyboard encoder. The switch has a common input line and two output signal lines. The two signal lines are complementary such that one line is always logic high and the other is always low. When the Remote Dose Cord button is pressed, both signal lines change to the alternate logic state. This redundancy prevents a single line failure from starting a dose delivery.

The (ON/OFF) button allows the pump to be placed in a very low power mode by turning off all sensors and LCD, but some battery energy is still used by the electronics. To maximize battery life, remove the batteries when pump is not in use.

Data Memory in Real Time Clock RAM

Many settings of the pump's delivery and record-keeping parameters are stored by the microprocessor in a Battery backed RAM in the Real Time Clock. Data to and from the memory is presented serially. Whenever the microprocessor uses data from the Real Time Clock, the data is checked for validity.

EEPROM

Data describing the current delivery protocol is stored in an EEPROM included in the microprocessor. Whenever this data is used, it is checked for validity.

Battery Backed RAM

Additional settings of the pump's delivery and record keeping parameters are stored in a battery backed Random Access Memory (RAM). Battery backup is provided by a printed circuit board-mounted lithium battery. This battery provides a minimum of five years of memory retention during normal pump usage. Whenever the microprocessor uses data from the RAM, the data is checked for validity.

Time Base Circuitry

An accurate 3.6864 MHz timebase is provided by a quartz crystal. The 3.6864 MHz signal is connected to the microprocessor, where it is frequency-divided to access the program memory at a cycle rate of 921 kHz.

In addition, an accurate 32.768 kHz timebase is provided by a second quartz crystal. The 32.768 kHz signal is used for the real time clock.

LCD Circuitry

The CADD-Legacy™ pumps feature a 2 line by 16 character Liquid Crystal Display (LCD). The characters on this dot matrix display are formed by a matrix of 5 by 7 dots. It is reflective only, with a black on silver appearance, with no backlight.

The display includes a controller chip mounted directly on the glass capable of interfacing with 4 and 8 bit systems to display 92 kinds of characters, numerals, symbols, and special characters under control of a built in character generator ROM. A RAM is also included to make other special characters possible.

LED Indicator

A green Light Emitting Diode (LED) is provided under the pump's front panel overlay to provide pump power status to the user. When this LED is lit, it indicates that an AC adapter is being used to power the pump.

Flash PROM Technology

Program memory for the pump is stored in Flash Programmable Read Only Memory (Flash PROM). This type of memory allows modification of the contents without physically removing the device from the circuit board. Under certain circumstances the program can also be downloaded. Several layers of redundancy in the programming system prevent accidental erasing or modification of the PROM.

Audible Alarm Circuitry

Audible alarm circuitry consists of two piezo electric disks and an independent oscillator. The disks flex or bend in resonance with the output of the oscillator. The piezo disks are mounted to the pump housing to enhance sound level.

The microprocessor controls the audible alarm by selecting the alarm control line for more than 0.5 seconds. The oscillator which drives the piezo disks is capable of providing two driving frequencies. The low frequency is in the range of 700 to 1500 Hz and the high frequency is in the range of 1600 to 2500 Hz. When the microprocessor selects the audible alarm, the alarm enters a warble mode where it oscillates between the low and high frequency sound at a rate of 0.8 and 2 Hz.

Low battery voltage detection and watchdog timer circuitry also have the ability to enable the audible alarm via the microprocessor.

The audible alarm circuitry is backed up by a super capacitor. The super capacitor provides energy for the alarm in the instance where all power is lost while pump is in the RUN mode. There is enough energy in the super capacitor to drive the audible alarm for 3 minutes when the pump has been in the RUN mode for 2 minutes or longer.

Watchdog Timer Circuit

Watchdog timer circuitry is provided to monitor the status of the microprocessor. If the microprocessor fails to function properly, the watchdog circuit issues a reset signal which disables the motor and enables the audible alarm. To assure proper function, the microprocessor must strobe the watchdog circuit at least once every second in order to prevent the watchdog from performing its reset function.

The reset output from the watchdog circuit is a pulse output. This acts to "jump start" the microprocessor. This unique feature allows the microprocessor to test the watchdog circuit on every power-up. By setting a flag in memory and not strobing the watchdog, the microprocessor can force a watchdog time-out. After being reset, the microprocessor checks the status flag to see if this was a time-out test. If so, the microprocessor verifies the watchdog's ability to disable the motor and then continues normal power-up activities.

If a reset occurs when the microprocessor is not expecting it, the microprocessor traps the event, sounds the audible alarm and displays an error message on the LCD.

Motor Drive/Motor Watchdog Circuit

The motor drive circuitry is composed of a series of power FET transistors, passive components, and two voltage comparators. Built into the motor drive circuitry is an RC timer which times how long the motor runs each time it is turned on. If the motor runs for more than an average of 4 seconds, the circuit will time out and disable the motor.

A unique feature of this circuit is that control lines to and from the microprocessor circuit allow the microprocessor to perform a complete functional test of the motor drive circuit without running the motor. The microprocessor performs this test function every several minutes to assure its continued functionality. An input from the watchdog circuit prevents motor operation if the watchdog timer expires.

Rotation of the motor is sensed by the microprocessor via an infrared-sensitive photo detector. An infrared light source is mounted

so that its light beam illuminates the infrared detector. An opaque flag is mounted concentrically to the camshaft and rotates with it between the infrared light source and detector.

When the flag interrupts the light beam, the output of the detector is sensed by the microprocessor via an input port bit. Power to the infrared LED light source is controlled by the motor drive circuit and is off when the motor is not running to conserve battery life.

In the microprocessor software, multiple checks are made on motion of the camshaft. When the motor is commanded to start, the infrared sensor must show that half a revolution has occurred within four seconds and that the motor has stopped when half a rotation was completed. In addition, no camshaft rotation can take place when the motor has not been commanded to run.

Power Circuitry

Power for the pump is normally supplied by two AA alkaline batteries, two AA lithium batteries, or an AC adapter. These types of batteries have a fairly low internal resistance over their discharge range, which will keep power supply noise low. Other types of batteries, such as carbon-zinc, exhibit high internal resistance, especially near depletion. A voltage drop across the internal resistance occurs when current is drawn by the motor during pump activations. This current is demanded in short pulses when the motor is first turned on and generates large spikes in the battery voltage. This noise can cause the low battery detection circuit to shut down the pump.

The power from the two AA batteries is boosted to +5VDC. This 5V is used to power the motor and a 3.3V linear regulator. The linear regulator provides power to all the other circuitry including the microprocessor.

Voltage Reference Circuit

A voltage reference circuit provides a constant DC voltage to the microprocessor Analog to Digital Converter (ADC). By reading this input and comparing the value to a predetermined range, the microprocessor can validate the accuracy of the 3.3-volt power supply. Variations in the 3.3-volt supply left undetected can result in inaccuracy in the low battery alarm set points and variations in other calculated values. (Also refer to Voltage Detector Circuit description on page 18.)

Pumping Mechanism

The pumping mechanism is linear peristaltic with two active valves and an expulsor. Pumping occurs when the expulsor presses on the reservoir pump tubing in sequence with the inlet and outlet valves. At rest, the outlet valve is pressing down fully on the tubing and the expulsor and inlet valve are retracted. (See Figure 9.)

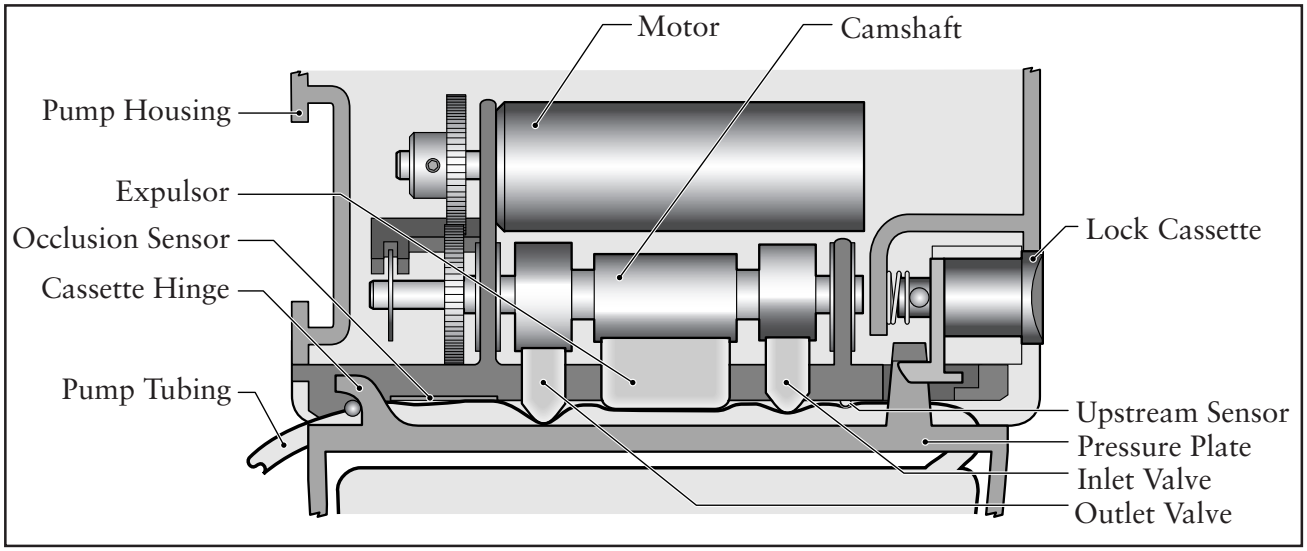

Figure 9. A simulated pumping mechanism in a CADD-Legacy™ pump.

When the microprocessor commands the mechanism to pump, the camshaft begins to rotate, thus controlling the following pump cycle:

1. The inlet valve closes.
2. In synchrony with the expulsor moving down to compress the tubing, the outlet valve opens, expelling 0.050 ml of fluid toward the patient.
3. The outlet valve closes.
4. The inlet valve opens as the expulsor is retracted, causing fluid from the reservoir to again fill the pump tubing segment.
5. The camshaft rotation stops after half a revolution and the cycle is completed.

Pumping Characteristics

To deliver the amount of drug specified by the parameter settings, the pump's microprocessor causes the pump mechanism to deliver fluid "pulses" timed according to the desired rate. At rates of 15 ml/hr or less the microprocessor delivers a single pulse to the motor circuit causing a half revolution of the camshaft and fluid delivery in 0.05 ml increments. At rates greater than 15 ml/hr the microprocessor delivers two back to back pulses to the motor circuit causing a full revolution of the camshaft and fluid delivery in 0.1 ml increments. Thus, to deliver 20 ml/hr, for example, the microprocessor solves these equations:

Mechanism activations per hr

= 20 ml per hr/0.1 ml per activation

= 20/0.1

= 200

Time (seconds) between activations

= 3600 sec per hr/number of activations per hr

= 3600/200

= 18

NOTE:

At rates 15 ml/hr the pump delivers 0.05 ml per stroke. This allows a more continuous delivery at low rates.

The microprocessor uses its timer circuits to accurately time the 18 seconds (in this example) between mechanism activations. The timebase accuracy is ultimately determined by the 3.6864 MHz quartz crystal oscillator.

Air Detector

The air detector is designed to detect air in the outlet tubing fluid path. The air detector can be set to On-high sensitivity, On-low sensitivity, or Off by accessing Biomed Functions. When the On-high sensitivity setting is selected the pump will detect a single bubble greater than 0.100 ml. When the On-low sensitivity setting is selected the pump will detect a single bubble greater than 0.250 ml.

Multi-bubble Sensing

The air detector is also designed to sense if an accumulation of more than 1 ml of air has passed through the outlet tubing path in the last 15 minutes. This feature is active anytime the air detector is on.

The air detector is compatible with all of the Medication Cassette™ Reservoirs and CADD® Administration Sets indicated for use with the CADD-Legacy™ pump, and all pump accessories. It is powered directly from the pump and no additional power is required.

Theory of Operation

The air detector consists of sensor electronics and two ultrasonic transducers positioned on opposite sides of the fluid path. One transducer acts as an acoustic transmitter and the other as an acoustic receiver. Air detection occurs when air in the fluid path causes a reduction in the signal level to the receiver. When the signal is interrupted for a preset length of time, the sensing circuitry sends a signal to the microprocessor indicating air in the fluid path. To maximize the reliability of the system and to reduce false alarms, the transmitted signal is swept over a frequency range. This accommodates varying resonance frequencies of the transducer and reduces sensitivity to tubing tolerances and other mechanical variations.

Downstream Occlusion Sensor

The downstream occlusion sensor is designed to detect excessive pressure in the outlet tubing.

If the fluid path to the patient becomes blocked, the pump tubing will expand as pumping occurs. When there has been an amount of inflation corresponding to 179.3 kPa ± 96.5 kPa, 1.79 (± 0.97) bar, or 26 (±14) psi, the occlusion sensor trips, whereupon the microprocessor stops the pump mechanism and issues visual and audible alarms. Thus the maximum pressure which can be developed is 276 kPa (2.76 bar, 40 psi).

Construction

The downstream occlusion sensor consists of a membrane switch located on the bottom of the pump next to the outlet valve. The switch is fastened to the housing with an adhesive to ensure that the overall assembly is water resistant.

Theory of Operation

The membrane switch is in contact with the outlet tubing when a cassette is installed. Tubing expansion caused by a downstream occlusion results in closure of the membrane switch. Switch closure sends a logic low to the microprocessor indicating a downstream occlusion.

Upstream Occlusion Sensor

The upstream occlusion sensor detects an occlusion in the inlet tubing which would prevent or restrict the flow of fluid to the pump.

Construction

The upstream occlusion sensor consists of a strain gauge sensor located on the bottom of the pump next to the inlet valve. The sensor is fastened to the housing with an adhesive to ensure that the overall assembly is water resistant.

Theory of Operation

When a cassette is installed on the pump, the inlet tubing is in contact with the sensor. In order to conserve battery power, the upstream occlusion sensor circuit is only activated while the motor circuitry is enabled. Pressure on the sensor is read just prior to the motor starting and after the end of the motor stroke. The microprocessor uses an average of the pressure exerted by the unoccluded tubing to establish a baseline pressure. If the tubing pressure at the end of a motor stroke is below the baseline pressure, the upstream tubing is occluded.

Cassette Attachment Detection

The pump uses the upstream occlusion sensor and cassette present sensor to verify the presence of a cassette. If an infusion is started by pressing (STOP START) when there is no cassette installed or if a cassette is improperly seated, the pump will initiate a visual and audible alarm.

Theory of Operation

During manufacture of the pump, upstream occlusion sensor readings are recorded for no cassette installed and typical cassette installed. These readings are used to calculate threshold levels for cassette detection. When a cassette is first attached to the pump, the new sensor reading must be above the calculated threshold level.

Additional readings are taken periodically while the pump is in use. If the sensor readings drop below the threshold when the motor is off, or the cassette present sensor circuit does not sense the presence of a cassette, the cassette is considered removed.

6 Safety Features and Fault Detection

Hardware Safety Features

Key hardware safety features include a watchdog timer circuit, motor drive and motor watchdog circuits, cassette present sensor circuit, and a voltage detector circuit. Each safety circuit performs a unique function to insure the overall safety of the device. (See Figure 10.)

Watchdog Timer Circuit

The microprocessor must send an appropriate signal to the watchdog circuit at least once per second. If the microprocessor does not, the watchdog circuit will time out and shut down the pump controller.

Watchdog timer circuitry is provided to monitor the status of the microprocessor and disable the motor and enable the audible alarm if the microprocessor fails to function properly. The microprocessor must strobe the watchdog circuit at least once every second in order to prevent the watchdog from performing its reset function. The reset output from watchdog circuit is a pulse output. This acts to "jump start" the microprocessor. This unique feature allows the microprocessor to test the watchdog circuit on every power-up. By setting a flag in memory and not strobing the watchdog, the microprocessor can force a watchdog time-out. After being reset, the microprocessor checks the status flag to see if this was a time-out test. If so, the microprocessor verifies the watchdog's ability to disable the motor and then continues normal power-up activities. If the reset occurred when the microprocessor was not expecting it, the microprocessor traps the event, sounds the audible alarm and displays an error message on the LCD.

Motor Drive/Motor Watchdog Circuit

Motor drive circuitry is composed of a series of power FET transistors, passive components, and two voltage comparators. Built into the motor drive circuitry is an RC timer which times how long the motor runs each time it is turned on. If the motor runs for more than an average of 4 seconds, the circuit will time out and disable the motor. A unique feature of this circuit is that control lines from the microprocessor can perform a complete functional test of the motor drive circuit without running the motor. The microprocessor performs this test function every several minutes to assure its continued functionality. An input from the watchdog circuit prevents motor operation if the watchdog timer expires.

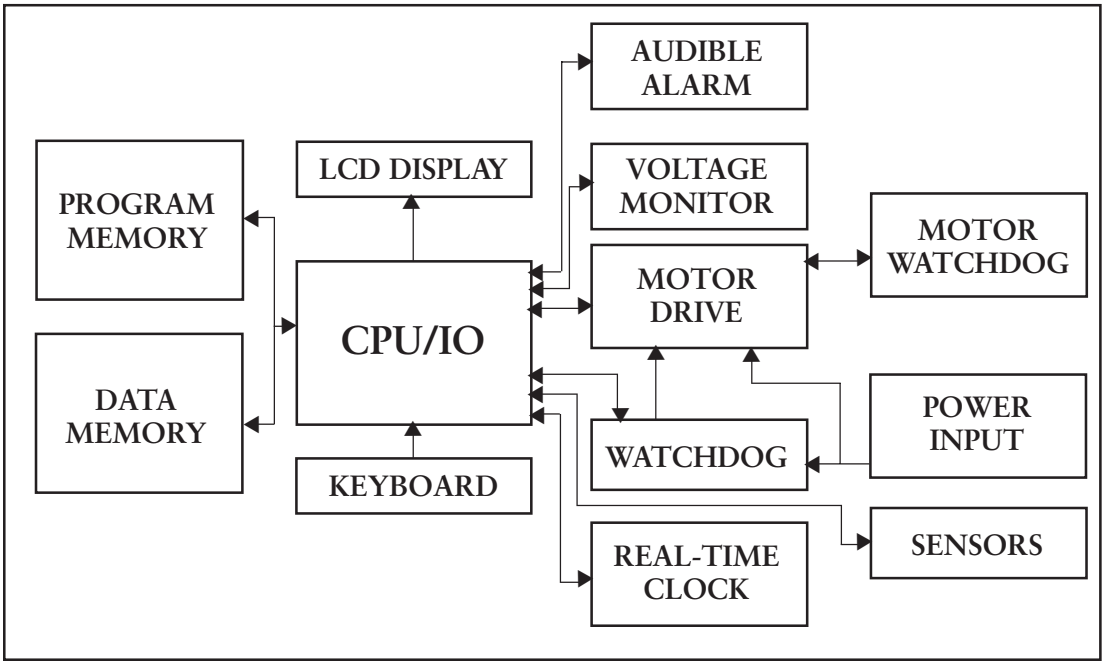

Figure 10. CADD-Legacy™ pump hardware block diagram.

Voltage Trip Point	Voltage Trip Point Source	Motor Status	CADD-Legacy™ Pump Status
2.4 V	Battery	Running/not running	No alarm
< 2.4 V	Battery	Not running	Audible alarm (3 beeps every 5 minutes); Low Bat message appears†
< 1.8 V	Battery	Running	Audible alarm (3 beeps every 5 minutes); Low Bat message appears†
< 4.75 V	5 Volt supply motor voltage	Running	Battery Depleted message appears††
< 1.0 V	Battery	Running/not running	Hardware reset occurs; Pump continues to indicate depleted battery condition

Table 9. CADD-Legacy™ pump low battery conditions.

Cassette Present Sensor Circuit

The cassette present sensor system consists of a switch on the pump mechanism that interfaces to the attached cassette and associated circuitry. This switch senses the presence of a cassette.

When a cassette is latched to the pump, the cassette presses against the switch in the pump mechanism. Electronic circuitry on the circuit board detects this and reports the information to the microprocessor. This system acts as a safety feature to detect a damaged or detached cassette. If, during operation, the microprocessor detects the switch open, the pump will enable audible and visual alarms and stop delivery.

Redundancy with the upstream occlusion sensor prevents single fault failures from causing over or under delivery of fluid. Additional circuitry allows these sensors to be turned on and off by the microprocessor to conserve battery power.

Voltage Detector Circuit

Low voltage detection is performed by part of the watchdog circuit and by the microprocessor via software. Three low voltage levels are detected. The first two levels (Low Battery and Battery Depleted) are detected by software and the third by hardware.

The first level to be reached is the Low Battery Warning threshold which occurs when the battery voltage decays to a nominal value of 2.4 volts when motor is off or 1.8 volts when motor is active. An Analog to Digital Converter (ADC) built into the microprocessor allows the microprocessor, via software, to monitor the battery voltage and motor voltage.

At the Low Battery Warning threshold, the microprocessor enables a periodic series of beeps and displays a “Low Bat” warning message on the LCD.

The second level is Battery Depleted Warning threshold. As the voltage operating the motor reaches a nominal value of 4.75 volts, the software disables delivery, places a “Battery Depleted” message on the LCD, and enables a continuous two tone audible alarm.

The third level is a hardware reset which is reached when the battery voltage decays to a nominal value of 1.0 volt. At this point a hardware reset circuit is triggered which places the microprocessor in reset. This prevents ambiguous microprocessor operation as the battery voltage continues to decay. The hardware reset continues until the battery is completely discharged or until it is removed. A hardware reset can only be cleared by replacing the old batteries with two fresh ones.

† The pump emits 3 beeps every 5 minutes, and the message “Low Bat” appears on the pump’s display, indicating that the battery power is low, but the pump is operable.

†† The pump emits a continuous, variable-tone alarm, and the message “Battery Depleted” appears on the display, the battery power is too low to operate the pump and pump operation has stopped.

Software Safety Features

Hardware-related Software Safety Features

Program Memory Check

At power up and at regular intervals thereafter, the program memory is tested by calculating a Cyclic Redundancy Code (CRC) on the program and then comparing it with the CRC stored with the program. If the stored and calculated CRCs do not match, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all drug delivery.

RAM Memory Check

At power up, the random access memory is checked. A particular bit pattern is written to and read from each address in the RAM. If the read data is different from the written data, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all drug delivery.

Motor Circuit Check

At power up and at regular intervals thereafter, the motor circuit is checked to ensure that no power is being applied to the motor unless the motor is actually on. If the software detects power being applied to the motor at any other time, it will sound a continuous two-tone audible alarm and will no longer attempt to deliver medication. During every pump activation, the software checks to see whether the motor completes one activation. If the motor fails to turn, or fails to complete a cycle, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all drug delivery.

Keypad Encoder Check

Key presses are routed to the microprocessor via a keypad encoder. Every time the software receives data from the keypad encoder, it is checked. If the data is not a valid key press, the software disregards it.

The keypad contains a redundant switch in the (STOP START) key, (PRIME) key, and (DOSE) key (CADD-Legacy™ PCA). The redundant switch in each of these keys is routed to the microprocessor via an I/O chip. The microprocessor must see a valid signal simultaneously from the redundant switch and the normal switch (routed through the keypad encoder) before it will start infusing.

Data Handling Software Safety Features

Data Stored in RAM

Before use, data associated with delivery and stored in RAM is tested by calculating a CRC on the data and then comparing it with the CRC stored with the data. If the stored and calculated CRCs do not match, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all drug delivery.

Data Stored in EEPROM

Before use, data associated with delivery and stored in EEPROM is tested by calculating a CRC on the data and then comparing it with the CRC stored with the data. If the stored and calculated CRCs do not match, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all drug delivery.

Data Stored in NOVRAM

Before use, data associated with delivery and stored in NOVRAM is tested by calculating a CRC on the data and then comparing it with the CRC stored with the data. If the stored and calculated CRCs do not match, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all drug delivery.

Data Used in Calculations

Calculations on data used in some way to control the delivery of drug are performed redundantly. The two calculated values are then compared. If the two values do not match, the software will display a system fault screen, turn on a continuous two-tone audible alarm, and stop all drug delivery.

Timer Data Registers

The data in the timer Real Time Clock is checked at regular intervals. If the data is not reasonable, the software will turn on a continuous two-tone audible alarm and stop all drug delivery.

7 Hardware and Software Fault Detection

Overview

If the CADD-Legacy™ pump displays an error code, a hardware or software fault has been detected by the microprocessor, and the pump should be returned for servicing.

When hardware or software faults are detected by the microprocessor, pump operation stops and a continuous two-tone audible alarm will be activated. An error message will be displayed on the LCD. On the next power up, the error code will again be displayed. If the error detected was a data fault, the pump will be in Lock Level 2, and all other programmed functions will have default values. (See the pump's *Operator's Manual* for specific defaults.)

Order of Error Code Events

1. There is a continuous two-tone audible alarm and the display will read

NOTE:

"XXXX" is a 4-digit code.

2. To silence the error code alarm, remove the batteries.
3. At each subsequent power up the pump will display the initial power up screen and then the following screen:

Thus there is always a display of the "Last Error Code (LEC)" detected by the microprocessor.

Error Code Range	Description
1010-1040	Software Application Errors
1110-1160	Software Control Errors
1210-1270	CRC Errors
1310-1340	Real Time Clock Errors
1410-1450	Standard Delivery Calculation Errors
1510-1530	Air Detector System Errors
1610-1670	CPU Test Errors
1710-1720	Miscellaneous Hardware Errors
1810-1872	Motor Errors

Table 10. CADD-Legacy™ pump error codes.

8 Cleaning and Inspection Procedures

Inspection Recommendation

Deltec recommends annual functional inspection on the CADD-Legacy™ 1, CADD-Legacy™ PLUS, and CADD-Legacy™ PCA pumps. The following inspection procedures should be performed annually to verify function and accuracy.

NOTE:

Persons performing the following tests and procedures should be familiar with the Deltec CADD-Legacy™ pump. Please read the Operator's Manual supplied with the pump before proceeding.

WARNING:

CADD-Legacy™ pumps are sealed units. A broken or damaged seal will, therefore, be considered conclusive evidence that the pump has been misused and/or altered, which voids any and all warranties. All service and repair of CADD-Legacy™ pumps must be performed by Deltec or its authorized agents.

Cleaning

Use any of the following solutions to clean the pump and accessories:

- Soap solution
- Benzalkonium chloride concentrate (0.13%)
- Glutaral concentrate, USP (2%)
- 10 percent solution of household bleach (one part household bleach to nine parts water)
- Alcohol, USP (93%)
- Isopropyl Alcohol, USP (99%)
- PDI - Super Sani-Cloth®
- Mada Medical - MadaCide
- 70% Chlorohexine

1. Dampen a soft, lint-free cloth with cleaning solution. Apply the solution to exterior surface of the pump or accessory. ***Do not allow the solution to soak into the pump or accessory***.
2. Wipe the entire surface dry with another soft, lint-free cloth. Allow the pump to dry completely before use.

CAUTION:

- **Do not immerse the pump in cleaning fluid or water. Do not allow solution to soak into the pump, accumulate on the keypad, or enter the battery compart-ment. Moisture build-up inside the pump may damage the pump.**
- **Do not clean the pump with acetone, other plastic solvents, or abrasive cleaners, as damage to the pump may occur.**

Battery Contact Cleaning

Pump battery contact cleaning can be performed easily using a clean cotton swab wetted with Isopropyl Alcohol or by using a pre-moistened Alcohol swab. Use a minimum of 70% concentration by volume Isopropyl Alcohol. **Do not use Alcohol formulation that has other additives besides Alcohol and water.**

- Using a cotton swab wetted with Alcohol or the pre-moistened Alcohol swab, rub with medium pressure over the entire contact surface a minimum of ten back and forth cycles (twenty total wipes over the contact).
- Select a fresh surface of the swab and repeat the cleaning process on the second battery contact. Dispose of the swab when finished.
- Using a second Alcohol wetted swab, rub over each contact surface again a minimum of four back and forth cycles (eight total wipes over the contact). Allow the contacts to dry for a few minutes.

Visual Inspection

- Visually inspect the pump for any damage to the LCD, occlusion sensor seals, valves and expulsor, cassette hinge area, cassette lock, cassette sensor, keypad, indicator light, power jack, accessory jack, air detector, and housing. If any damage is noted, the pump should be returned for service.
- Check the battery door for proper operation. It should not be broken or damaged. The battery door mating tabs on the pump housing should not be broken or damaged.
- Examine the battery compartment for damage. If the battery contacts appear corroded, clean them as instructed on page 20. If the battery contacts appear to be bent or pushed in, straightening may be possible with a small screwdriver or other suitable tool. Care must be taken not to damage the pump housing or to incur further damage to the contacts.

Mechanical Inspection

- Press each key on the keypad. Each key should have a distinctive dome feeling. The keys should not feel flat.
- Attach the battery door. The battery door should fit snugly in place when it is closed on the pump.
- Attach either a 50-ml or 100-ml Medication Cassette™ Reservoir or a CADD® Administration Set to the pump. Using a coin (key for the CADD-Legacy™ PCA pump), turn the lock 1/4 turn counter-clockwise. Check for smooth operation and a definite feel when the lock pulls the cassette firmly against the bottom of the pump. The slot on the cassette lock should be aligned with the “LOCKED” indicator on the side of the pump.
- Gently twist and pull on the cassette to make sure it is firmly attached.

9 Testing Procedures

Testing Recommendation

Deltec recommends annual functional testing on the CADD-Legacy™ pumps. The following testing procedures should be performed annually to verify function and accuracy.

NOTE:

To perform the following functional tests the pump must be in Lock Level 0.

Changing to Lock Level 0 (LL0)

Before programming the pump, make sure the lock level is 0. LL0 allows the operator to access all programming and operating functions.

1. Make sure the pump is stopped. Press LOCK. The current lock level will appear. (If the lock level is already LL0, press NEXT to exit.)
2. Press ▲ or ▼ until "LL0" appears.
3. Press LOCK again or ENTER CLEAR. "Code 0" will appear.
4. Press ▲ or ▼ until the Lock Level Code "63" appears for CADD-Legacy™ PCA, "64" for CADD-Legacy™ 1 or "65" for CADD-Legacy™ PLUS.
5. Press LOCK or ENTER CLEAR to set the new lock level.

CADD-Legacy™ PCA Pump

Power-up Check

- Insert batteries or press ON OFF and observe the LCD during power up. The first screen will display the serial number, model number, and software number with revision level. The second screen will display 32 character blocks. (If "LEC" and four digits appear prior to the pump displaying the 32 character blocks, the pump has experienced an electrical or mechanical fault and should be returned for service.) If no error message is immediately shown, the pump has powered up normally. The pump will then sequentially display all of the programmed values and beep at each screen. After all screens are displayed, successful power up is indicated with six audible beeps and the "STOPPED" screen displayed. Continue with the Lock check.

To Access Biomed Functions Loop

1. Press LOCK. The current lock level will appear.
2. Press LOCK or ENTER CLEAR. "CODE 0" will appear.
3. Press ▲ or ▼ until the Biomed function code "163" appears (Lock Code +100). Then press LOCK or ENTER CLEAR.

Air Detector ON/OFF

1. Press NEXT until "Air Detector" appears.
2. Use ▲ or ▼ to select "Off."
3. Press ENTER CLEAR to enter the change.

Lock Check

- Attach a 50- or 100-ml Medication Cassette™ Reservoir or a CADD® Administration Set to the pump. The mark on the Cassette Lock button should be aligned with the "Locked" symbol.

Cassette Sensor Check

- Unlock the cassette by inserting a key into the lock and turning clockwise.
- The pump should issue an audible alarm and the display should read "No Disposable Clamp Tubing".
- Press STOP START or NEXT to silence the alarm. Press and hold ON OFF to turn the pump off.

The following three checks (LCD, Motor and Gear Train, and Reservoir Volume Empty Alarm Check) should be performed in the sequence shown.

LCD Check

- With the pump turned off, press ON OFF. The second screen that the pump displays will consist of 32 blocks of characters. Examine the LCD to verify that there are no missing dark pixels in the character blocks.

Motor and Gear Train Check

- Program the Reservoir Volume to 2.0 ml.
- Attach either a 50- or 100-ml Medication Cassette™ Reservoir or CADD® Administration Set to the pump. Lock the cassette.
- Press and hold (PRIME) until three series of dashes appear. Release (PRIME). Press and hold (PRIME). While priming the pump, listen to the motor for excessive noise or grinding sounds. Count the number of pump activations. The pump should prime ten double activations and then stop. Press (NEXT) to return to main menu.

Reservoir Volume Empty Alarm Check

- Program the Reservoir Volume to 1.0 ml. Press (NEXT) until Reservoir Volume is displayed on the LCD. Press (▲) or (▼) until 1.0 ml is displayed. Then press (ENTER CLEAR).
- Press and hold (PRIME) until three series of dashes appear. Release (PRIME). Press and hold (PRIME). The pump should prime ten double activations and then stop. The pump will alarm and display "Reservoir Volume Empty." Press (NEXT).

Starting/Stopping the Pump

- Program the pump with the following values:
  Reservoir Volume: 1.0 ml
  Units: milliliters
  Continuous Rate: 50 ml/hr
  Demand Dose: 0.00 ml
  Given: 0.00 (Press (ENTER CLEAR))
- Program the Air Detector Off.
- Press and hold (STOP START). "Starting" appears followed by three sets of dashes, each accompanied by a beep. A review of the programmed parameters then appears. The main screen should appear with "RUN" in the display.
- To stop the device, press and hold (STOP START). "Stopping" appears followed by three sets of dashes that disappear one at a time, each accompanied by a beep. The main screen should appear with "STOPPED" in the display.

Activation Timing Check

- Reprogram the Reservoir Volume to 1.0 and clear the Given screen.
- Press and hold (STOP START) until three dashes disappear from the display. The pump should sequentially display all of the programmed values. Start a timer at the first motor activation.
- Count the activations. One activation should occur every six seconds. Approximately sixty-six seconds and ten activations later, the Reservoir Volume alarm should occur. The display should show "Reservoir Volume Empty."

DOSE Key Check (CADD-Legacy™ PCA pump only)

- Check the (DOSE) key operation by programming the pump with the following values:

Reservoir Volume:	10.0 ml
Units:	Milliliters
Continuous Rate:	0.0 ml/hr
Demand Dose:	1.00 ml
Dose Lockout:	00 hrs 5 min
Doses Per Hour:	12
Doses Given:	0 doses (Press (ENTER CLEAR) to clear)
Doses Attempted:	0 doses (Press (ENTER CLEAR) to clear)
Given:	0.00 ml (Press (ENTER CLEAR) to clear)

- Press and hold (STOP START). The pump should sequentially display all of the programmed values.
- After "RUN" appears on the display, press (DOSE) and note the time. The pump should beep twice and begin to deliver. Count the number of pump activations. The pump should make ten double activations. After ten double activations, the display should show a Reservoir Volume of 9.0 ml. Press (DOSE) two more times within the next 5 minutes. The pump should not deliver.

Remote Dose Cord Check (CADD-Legacy™ PCA pump only)

- Wait 5 minutes after the dose given above; then, instead of pressing (DOSE), press the button on the Remote Dose Cord. The pump should make ten double activations. After ten double activations, the display should show a Reservoir Volume of 8.0 ml. Press

the Remote Dose Cord button two more times within the next 5 minutes. The pump should not deliver.

Doses Given and Doses Attempted Check (CADD-Legacy™ PCA pump only)

- Stop the pump by pressing and holding (STOP START). Use (NEXT) to advance to the Doses Given screen. The screen should show 2. Use (NEXT) to advance to the Doses Attempted screen. The display should show 6. (If the above steps have not been followed exactly, different values may appear.)

GIVEN Mode Check

- Press (NEXT) to advance to the Given screen. The display should now show 2.00 ml. (If the above steps have not been followed exactly, a different value may appear.)
- Press the (ENTER CLEAR) key. The display should now show 0.00 ml.

Air Detector Test

This test will verify the function of the air detector. To perform this test, the air detector must be turned on. The previous program from the (DOSE) key check can be used to perform this test.

- Attach an empty Medication Cassette™ Reservoir or CADD® Administration Set to the pump.
- Secure it using the lock button.
- Thread the tubing through the air detector groove.
- Start the pump.
- The pump should respond with a continuous two-tone alarm and the display should read:

  "Air In Line Detected"

- Press (NEXT) or (STOP START) to silence the alarm, and remove the Medication Cassette™ Reservoir or CADD® Administration Set.
- Now attach a Medication Cassette™ Reservoir containing fluid, or a primed CADD® Administration Set to the pump. Make certain there is no air in the fluid path.
- Secure it using the lock button.
- Thread the tubing through the air detector groove.
- Start the pump.
- Deliver a demand dose. (NOTE: Five minutes must have passed since the delivery of the last demand dose.)
- The pump should deliver the dose without an air detection alarm.

Upstream Occlusion Sensor Test

- Verify that the Upstream Occlusion Sensor is turned on. (See page 23, To Access Biomed Functions Loop.)
- Obtain a CADD® Administration Set with bag spike and anti-siphon valve. Also obtain a clamp (slide clamp or hemostat).
- Insert the CADD® Administration Set spike into an appropriate, standard IV bag filled with water. Attach the cassette to the pump. Prime the entire fluid path.
- Program the pump to deliver a continuous maximum rate. Press and hold (STOP START) to start the pump.
- Clamp the tubing halfway between the IV bag and the pump. The pump should alarm within three activations after clamping the tubing.

Occlusion Pressure Range Tests

Occlusion Pressure Range Test I

Description

Pressure is generated by activating the pumping mechanism with an attached filled, clamped Medication Cassette™ Reservoir. The pump is started and a Demand Dose is given until the high pressure alarm sounds.

Equipment needed

50- or 100-ml Medication Cassette™ Reservoir containing distilled water

Procedure

1. Insert two AA batteries and wait for the pump to power up.
2. Attach a Medication Cassette™ Reservoir containing water to the pump. Lock the cassette.

3. Prime the Medication Cassette™ Reservoir tubing. The tubing should be filled with fluid to the end of the luer lock connector. The system ***must*** be free from air bubbles for this test.
4. Close the slide clamp on the distal end of the tubing near the female luer of the Medication Cassette™ Reservoir.
5. Program the pump to the following parameters:

Reservoir Volume:	10.0 ml
Units:	Milliliters
Continuous Rate:	0.00 ml/hr
Demand Dose:	1.00 ml
Dose Lockout:	00 hrs 5 min
Doses Per Hour:	12
Dose Given:	0 (Press ENTER CLEAR to clear)
Dose Attempts:	0 (Press ENTER CLEAR to clear)
Milligrams Given:	0.00 ml (Press ENTER CLEAR to clear)

6. Start the pump. When the pump is running, activate a Demand Dose, noting when the high pressure alarm is activated.
7. The pump should alarm when the pump delivers between 1 and 2 activations.

Occlusion Pressure Range Test II

Description

An adjustable metered pressure source is connected to the Medication Cassette™ Reservoir tubing. The pressure is slowly increased until the high pressure alarm sounds.

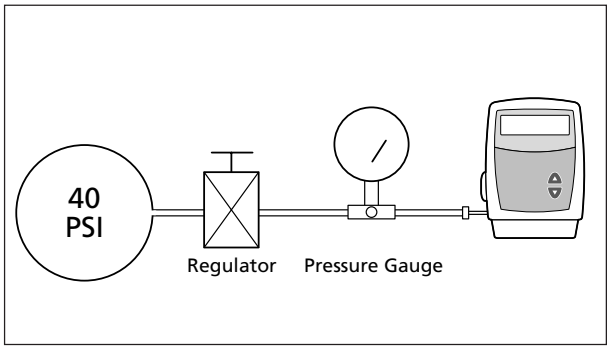

Figure 11. Occlusion test set-up.

Equipment needed

- Pressure gauge, 40 psi ± 1 psi (2.76 bar ± 0.07 bar)
- Pressure vessel, partially filled with water
- Pressure regulator, 40 psi (2.76 bar ± 0.07 bar)
- 50 or 100 ml Medication Cassette™ Reservoir containing water

CAUTION:

At the completion of the test, the pressure must be reduced to zero before detaching the cassette from the pump; otherwise, the cassette may rupture. Safety glasses should be worn while conducting or observing this test.

Procedure

1. Insert two AA batteries and wait for the pump to power up.
2. Attach a Medication Cassette™ Reservoir to the pump. Lock the cassette.

NOTE:

The pressure from the source must be zero when the cassette is attached.

3. Assemble the apparatus as shown in Figure 11.
4. Connect the Medication Cassette™ Reservoir outlet tube to the metered pressure source.

NOTE:

Do not use a CADD® Extension Set with Anti-siphon Valve.

5. Program the pump for a continuous rate of 50 ml/hr. Press STOP START.
6. Slowly increase the back pressure, noting when the high pressure alarm is activated.

NOTE:

The pressure may be increased rapidly to 8 psi (0.55 bar), after which the pressure should be increased at 3 psi/min (0.21 bar/min) or less until the alarm sounds.

7. The high pressure alarm should sound within 1.79 (±0.97) bar, or 26 (±14) psi.

Accuracy Testing

Gravimetric Accuracy Testing

Description

A Medication Cassette™ Reservoir is partially filled with water and weighed. The cassette is then attached to the pump and the pump is set to deliver a certain amount of water. The cassette is then removed and weighed again. The amount of water delivered is compared to the amount that the pump should have delivered.

Nominal system accuracy is given in the technical specifications section for the pump. That is, under the test conditions described below, the accuracy of the pump and Medication Cassette™ Reservoir will be nominal with a 90% confidence level. The nominal test conditions are as follows: degassed water at 25 ± 5°C without back pressure.

Equipment needed

- 50- or 100-ml Medication Cassette™ Reservoir
- 50 or 60 ml syringe
- CADD® Extension Set with Anti-siphon Valve
- A balance accurate to 0.1 g
- 40 ml of room temperature water

Procedure

1. Fill the 50 or 60 ml syringe with 40 ml of water. Transfer the water into a Medication Cassette™ Reservoir.
2. Remove any air from the Medication Cassette™ Reservoir by aspirating the air with the syringe. Attach the CADD® Extension Set with Anti-siphon Valve. Prime the tubing so it is filled with fluid to the end of the CADD® Extension Set luer lock connector.
3. Weigh the entire Medication Cassette™ Reservoir/CADD® Extension Set assembly and record the weight. This is the **pre-delivery weight**. (This weight includes the empty Medication Cassette™ Reservoir, CADD® Extension Set, and weight of the water.)
4. Attach the Medication Cassette™ Reservoir to the pump. Program the reservoir volume to 20 ml. Now press (ENTER CLEAR). This value is the **intended delivery volume**. Remove the slide clamp.
5. With the pump in Lock Level 0, program a continuous rate of 50 ml/hr. Start the pump and deliver 20 ml.
6. Again, secure the slide clamp as close as possible to end of the CADD® Extension Set luer lock connector. Remove the Medication Cassette™ Reservoir from the pump and weigh the entire Medication Cassette™ Reservoir/CADD® Extension Set assembly. This is the **post-delivery weight**.
7. Calculate the difference in weight between the pre-delivery weight and the post-delivery weight. This is the **weight of the amount delivered**. (1 ml of water at 20° weighs 1 gram.)
8. Find the difference between the volume of the amount delivered and the intended delivery volume. This is the **inaccuracy volume**.
9. Divide the inaccuracy volume by the intended delivery volume and multiply by 100. This is the **accuracy error percentage**. (See Table 11.)
10. If the accuracy error percentage is greater than ± 6%, repeat the test with a new Medication Cassette™ Reservoir. If the pump fails a second time, call Deltec's Customer Service Department.

Pre-Delivery Weight	Post-Delivery Weight	Weight of Amount Delivered	Intended Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error Percentage
61.1 g	41.6 g	19.5 g = 19.5 ml	20 ml	-0.5 ml	-0.5 ml ÷ 20.0 ml = -0.025	-0.025 x 100 = -2.5%

Table 11. Gravimetric percentage calculation

Example:

Pre-delivery Weight:	61.1 g
Post-delivery Weight:	– 41.6 g
Weight of Amount Delivered:	19.5 g
	= 19.5 ml
Volume of Amount Delivered:	19.5 ml
Intended Delivery Volume:	– 20.0 ml
Inaccuracy Volume:	**-0.5 ml**
Inaccuracy Volume:	-0.5 ml
Intended Delivery Volume:	÷ 20.0 ml
Accuracy Error:	-0.025
	x 100.00
Accuracy Error Percentage	**= -2.5%**

Volumetric Accuracy Testing

Description:

A predetermined amount of water is delivered into a collection device such as a burette or graduated cylinder. The amount of water delivered is compared to the amount that the pump should have delivered.

Nominal system accuracy is given in the technical specifications section for the pump. That is, under the test conditions described below, the accuracy of the pump and Medication Cassette™ Reservoir will be nominal with a 90% confidence level. The nominal test conditions are as follows: degassed water at 25 ± 5°C without back pressure.

Equipment needed:

- 50- or 100- ml Medication Cassette™ Reservoir
- 50- or 60- ml syringe
- CADD® Extension Set with Anti-siphon Valve
- A fluid collection device such as a burette or a class A 25 ml capacity graduated cylinder
- 40 ml of room temperature water

NOTE:

The test procedure calls for the use of a Medication Cassette™ Reservoir and a CADD® Extension Set with Anti-siphon Valve. An IV bag and CADD® Administration Set with integral or add-on anti-siphon valve can be substituted for the Medication Cassette™ Reservoir and CADD® Extension Set with Anti-siphon Valve.

Procedure:

1. Fill the 50- or 60-ml syringe with 40 ml of water. Transfer the water into a Medication Cassette™ Reservoir.
2. Remove any air from the Medication Cassette™ Reservoir by aspirating the air with the syringe. Attach the CADD® Extension Set with Anti-siphon Valve. Prime the tubing so it is filled with fluid to the end of the CADD® Extension Set luer lock connector.
3. Insert the end of the CADD® Extension Set into the fluid collection device.
4. Attach the Medication Cassette™ Reservoir to the pump. Program the Reservoir Volume to 20 ml. This is the **intended delivery volume**. Remove all clamps.
5. Program a continuous rate of 50 ml/hr. Start the pump and deliver 20 ml.
6. When delivery is complete, record the volume of fluid delivered. This is the **actual delivery**.
7. Find the difference between the volume of the amount delivered and the intended delivery volume. This is the **inaccuracy volume**.
8. Divide the inaccuracy volume by the intended delivery volume and multiply by 100. This is the **accuracy error percentage**. (See Table 12.)

Intended Delivery Volume	Actual Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error Percentage
20 ml	19.5 ml	-0.5 ml	-0.5 ml ÷ 20.0 ml = -0.025	-0.025 x 100 = -2.5%

Table 12. Volumetric percentage calculation

9. If the accuracy error percentage is greater than ± 6%, repeat the test with a new Medication Cassette™ Reservoir. If the pump fails a second time, call Deltec's Customer Service Department.

Example:

Actual Delivery Volume:	19.5 ml
Intended Delivery Volume:	– 20.0 ml
Inaccuracy Volume:	**= -0.5 ml**
Inaccuracy Volume:	-0.5 ml
Intended Delivery Volume:	÷ 20.0 ml
Accuracy Error:	**-0.025**
	x 100.00
Accuracy Error Percentage:	**= -2.5%**

CADD-Legacy™ 1 Pump

Power-up Check

- Insert batteries or press (ON/OFF) and observe the LCD during power up. The first screen will display the serial number, model number, and software number with revision level. The second screen will display 32 character blocks. (If "LEC" and four digits appear prior to the pump displaying the 32 character blocks, the pump has experienced an electrical or mechanical fault and should be returned for service.) If no error message is immediately shown, the pump has powered up normally. The pump will then sequentially display all of the programmed values and beep at each screen. After all screens are displayed, successful power up is indicated with six audible beeps and the "STOPPED" screen displayed. Continue with the Lock check.

To Access Biomed Functions Loop

1. Press (LOCK). The current lock level will appear.
2. Press (LOCK) or (ENTER/CLEAR). "CODE 0" will appear.
3. Press (▲) or (▼) until the Biomed function code "164" appears (Lock Code +100). Then press (LOCK) or (ENTER/CLEAR).

Air Detector ON/OFF

1. Press (NEXT) until "Air Detector" appears.
2. Use (▲) or (▼) to select "Off."
3. Press (ENTER/CLEAR) to enter the change.

Lock Check

- Attach a 50- or 100-ml Medication Cassette™ Reservoir or a CADD® Administration Set to the pump. The slot on the Cassette Lock button should be aligned with the "Locked" symbol.

Cassette Sensor Check

- Unlock the cassette by inserting a coin into the latch and turning clockwise.
- The pump should issue an audible alarm and the display should read "No Disposable Clamp Tubing".
- Press (STOP/START) or (NEXT) to silence the alarm. Press and hold (ON/OFF) to turn the pump off.

The following three checks (LCD, Motor and Gear Train, and Reservoir Volume Empty Alarm Check) should be performed in the sequence shown.

LCD Check

- With the pump turned off, press (ON/OFF). The second screen that the pump displays will consist of 32 blocks of characters. Examine the LCD to verify that there are no missing dark pixels in the character blocks.

Motor and Gear Train Check

- Program the Lock Level to LL0. Program the Reservoir Volume to 2.0 ml.
- Attach either a 50- or 100-ml Medication Cassette™ Reservoir or CADD® Administration Set to the pump. Lock the cassette.
- Press and hold (PRIME) until three series of dashes appear. Release (PRIME). Press and hold (PRIME). While priming the pump, listen to the motor for excessive noise or grinding sounds. Count the number of pump activations. The pump should prime ten double activations and then stop. Press (NEXT) to return to the main menu.

Reservoir Volume Empty Alarm Check

- Program the Reservoir Volume to 1.0 ml.
- Press and hold (PRIME) until three series of dashes appear. Release (PRIME). Press and hold (PRIME). The pump should prime ten double activations and then stop. The pump will alarm and display "Reservoir Volume Empty." Press (NEXT).

Starting/Stopping the Pump

- Program the pump with the following values:

Reservoir Volume:	1.0 ml
Rate:	3000 ml/24hrs
Given:	0.0 ml (press ENTER CLEAR to clear)

- Program the Air Detector Off.
- Press and hold STOP START. "Starting" appears followed by three sets of dashes, each accompanied by a beep. A review of the programmed parameters then appears. The main screen should appear with "RUN" in the display.
- To stop the device, press and hold STOP START. "Stopping" appears followed by three sets of dashes that disappear one at a time, each accompanied by a beep. The main screen should appear with "STOPPED" in the display.

Activation Timing Check

- Reprogram the Reservoir Volume to 1.0 and clear the Given screen.
- Press and hold STOP START until three dashes disappear from the display. The pump should sequentially display all of the programmed values. Start a timer at the first motor activation.
- Count the activations. One activation should occur every three seconds. Approximately twenty-seven seconds and ten activations later, the Reservoir Volume alarm should occur. The display should show "Reservoir Volume Empty."

GIVEN Mode Check

- Press NEXT to advance to the Given screen. The display should now show 1.00 ml. (If the above steps have not been followed exactly, a different value may appear.)
- Press the ENTER CLEAR key. The display should now show 0.00 ml.

Air Detector Test

This test will verify the function of the air detector. To perform this test, the air detector must be turned on. The previous program from the Activation Timing Check can be used to perform this test.

- Attach an empty Medication Cassette™ Reservoir or CADD® Administration Set to the pump.
- Secure it using the lock button.
- Thread the tubing through the air detector groove.
- Start the pump.
- The pump should respond with a continuous two-tone alarm and the display should read:

  "Air In Line Detected"

- Press NEXT or STOP START to silence the alarm, and remove the Medication Cassette™ Reservoir or CADD® Administration Set.
- Now attach a Medication Cassette™ Reservoir containing fluid or a primed CADD® Administration Set to the pump. Make certain there is no air in the fluid path.
- Secure it using the lock button.
- Thread the tubing through the air detector groove.
- Program the Reservoir Volume to 1.0 ml. Start the pump.
- The pump should deliver without an air detection alarm.

Upstream Occlusion Sensor Test

- Verify that the Upstream Occlusion Sensor is turned on. (See page 29, To Access Biomed Functions Loop.)
- Obtain a CADD® Administration Set with bag spike and anti-siphon valve. Also obtain a clamp (slide clamp or hemostat).
- Insert the CADD® Administration Set spike into an appropriate, standard IV bag filled with water. Attach the cassette to the pump. Prime the entire fluid path.
- Program the pump to deliver a continuous maximum rate. Press and hold STOP START to start the pump.
- Clamp the tubing halfway between the IV bag and the pump. The pump should alarm within three activations after clamping the tubing.

Occlusion Pressure Range Tests

Occlusion Pressure Range Test I

Description

Pressure is generated by activating the pumping mechanism with an attached filled, clamped Medication Cassette™ Reservoir. The pump is started and a Demand Dose is given until the high pressure alarm sounds.

Equipment needed

50- or 100-ml Medication Cassette™ Reservoir containing distilled water.

Procedure

1. Insert two AA batteries and wait for the pump to power up.
2. Attach a Medication Cassette™ Reservoir containing water to the pump. Lock the cassette.
3. Prime the Medication Cassette™ Reservoir tubing. The tubing should be filled with fluid to the end of the luer lock connector. The system ***must*** be free from air bubbles for this test.
4. Close the slide clamp on the distal end of the tubing near the female luer of the Medication Cassette™ Reservoir.
5. Program the pump to the following parameters:

Reservoir Volume:	10.0 ml
Continuous Rate:	3000.0 ml/24hr
Given:	0.0 ml (Press ENTER CLEAR to clear)

6. Start the pump. When the pump is running, note when the high pressure alarm is activated.

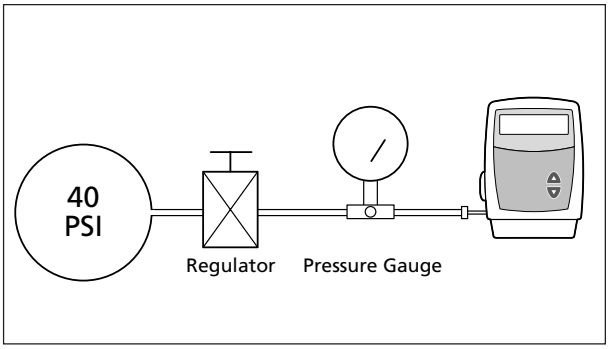

Figure 12 . Occlusion test set-up.

7. The pump should alarm when the pump delivers between 1 and 2 activations.

Occlusion Pressure Range Test II

Description

An adjustable metered pressure source is connected to the Medication Cassette™ Reservoir tubing. The pressure is slowly increased until the high pressure alarm sounds.

Equipment needed

- Pressure gauge, 40 psi ± 1 psi (2.76 bar ± 0.07 bar).
- Pressure vessel, partially filled with water.
- Pressure regulator, 40 psi (2.76 bar ± 0.07 bar).
- 50 or 100 ml Medication Cassette™ Reservoir containing water.

CAUTION:

At the completion of the test, the pressure must be reduced to zero before detaching the cassette from the pump; otherwise, the cassette may rupture. Safety glasses should be worn while conducting or observing this test.

Procedure

1. Insert two AA batteries and wait for the pump to power up.
2. Attach a Medication Cassette™ Reservoir to the pump. Lock the cassette.

NOTE:

The pressure from the source must be zero when the cassette is attached.

3. Assemble the apparatus as shown in Figure 12.
4. Connect the Medication Cassette™ Reservoir outlet tube to the metered pressure source.

NOTE:

Do not use a CADD® Extension Set with Anti-siphon Valve.

5. Program the pump for a continuous rate of 3000 ml/24hr. Press STOP START.
6. Slowly increase the back pressure, noting when the high pressure alarm is activated.

NOTE:

The pressure may be increased rapidly to 8 psi (0.55 bar), after which the pressure should be increased at 3 psi/min (0.21 bar/min) or less until the alarm sounds.

7. The high pressure alarm should sound within 1.79 (±0.97) bar, or 26 (±14) psi.

Accuracy Testing

Gravimetric Accuracy Testing

Description

A Medication Cassette™ Reservoir is partially filled with water and weighed. The cassette is then attached to the pump and the pump is set to deliver a certain amount of water. The cassette is then removed and weighed again. The amount of water delivered is compared to the amount that the pump should have delivered.

Nominal system accuracy is given in the technical specifications section for the pump. That is, under the test conditions described below, the accuracy of the pump and Medication Cassette™ Reservoir will be nominal with a 90% confidence level. The nominal test conditions are as follows: degassed water at 25 ± 5°C without back pressure.

Equipment needed

- 50- or 100-ml Medication Cassette™ Reservoir
- 50 or 60 ml syringe
- CADD® Extension Set with Anti-siphon Valve
- A balance accurate to 0.1 g
- 40 ml of room temperature water

Procedure

1. Fill the 50 or 60 ml syringe with 40 ml of water. Transfer the water into a Medication Cassette™ Reservoir.
2. Remove any air from the Medication Cassette™ Reservoir by aspirating the air with the syringe. Attach the CADD® Extension Set with Anti-siphon Valve. Prime the tubing so it is filled with fluid to the end of the CADD® Extension Set luer lock connector.
3. Weigh the entire Medication Cassette™ Reservoir/CADD® Extension Set assembly and record the weight. This is the **pre-delivery weight**. (This weight includes the empty Medication Cassette™ Reservoir, CADD® Extension Set, and weight of the water.)
4. Attach the Medication Cassette™ Reservoir to the pump. Program the reservoir volume to 20 ml. Now press (ENTER CLEAR). This value is the **intended delivery volume**. Remove the slide clamp.
5. With the pump in Lock Level 0, program a continuous rate of 3000 ml/24hr. Start the pump and deliver 20 ml.
6. Again, secure the slide clamp as close as possible to end of the CADD® Extension Set luer lock connector. Remove the Medication Cassette™ Reservoir from the pump and weigh the entire Medication Cassette™ Reservoir/CADD® Extension Set assembly. This is the **post-delivery weight**.
7. Calculate the difference in weight between the pre-delivery weight and the post-delivery weight. This is the **weight of the amount delivered**. (One ml of water at 20°C weighs 1 gram.)
8. Find the difference between the volume of the amount delivered and the intended delivery volume. This is the **inaccuracy volume**.

Pre-Delivery Weight	Post-Delivery Weight	Weight of Amount Delivered	Intended Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error Percentage
61.1 g	41.6 g	19.5 g = 19.5 ml	20 ml	-0.5 ml	-0.5 ml ÷ 20.0 ml = -0.025	-0.025 x 100 = -2.5%

Table 13. Gravimetric percentage calculation

9. Divide the inaccuracy volume by the intended delivery volume and multiply by 100. This is the **accuracy error percentage**. (See Table 13.)
10. If the accuracy error percentage is greater than ± 6%, repeat the test with a new Medication Cassette™ Reservoir. If the pump fails a second time, call Deltec's Customer Service Department.

Example:

Pre-delivery Weight:	61.1 g
Post-delivery Weight:	– 41.6 g
Weight of Amount Delivered:	**19.5 g**
	= 19.5 ml
Volume of Amount Delivered:	19.5 ml
Intended Delivery Volume:	– 20.0 ml
Inaccuracy Volume:	**= -0.5 ml**
Inaccuracy Volume:	-0.5 ml
Intended Delivery Volume:	÷ 20.0 ml
Accuracy Error:	**-0.025**
	x 100.00
Accuracy Error Percentage:	**= -2.5%**

Volumetric Accuracy Testing

Description:

A predetermined amount of water is delivered into a collection device such as a burette or graduated cylinder. The amount of water delivered is compared to the amount that the pump should have delivered.

Nominal system accuracy is given in the technical specifications section for the pump. That is, under the test conditions described below, the accuracy of the pump and Medication Cassette™ Reservoir will be nominal with a 90% confidence level. The nominal test conditions are as follows: degassed water at 25 ± 5°C without back pressure.

Equipment needed:

- 50- or 100- ml Medication Cassette™ Reservoir
- 50- or 60- ml syringe
- CADD® Extension Set with Anti-siphon Valve
- A fluid collection device such as a burette or a class A 25 ml capacity graduated cylinder
- 40 ml of room temperature water

NOTE:

The test procedure calls for the use of a Medication Cassette™ Reservoir and a CADD® Extension Set with Anti-siphon Valve. An IV bag and CADD® Administration Set with integral or add-on anti-siphon valve can be substituted for the Medication Cassette™ Reservoir and CADD® Extension Set with Anti-siphon Valve.

Procedure:

1. Fill the 50- or 60-ml syringe with 40 ml of water. Transfer the water into a Medication Cassette™ Reservoir.
2. Remove any air from the Medication Cassette™ Reservoir by aspirating the air with the syringe. Attach the CADD® Extension Set with Anti-siphon Valve. Prime the tubing so it is filled with fluid to the end of the CADD® Extension Set luer lock connector.
3. Insert the end of the CADD® Extension Set into the fluid collection device.
4. Attach the Medication Cassette™ Reservoir to the pump. Program the Reservoir Volume to 20 ml. This is the **intended delivery volume**. Remove all clamps.
5. Program a continuous rate of 3000 ml/24hr. Start the pump and deliver 20 ml.
6. When delivery is complete, record the volume of fluid delivered. This is the **actual delivery**.
7. Find the difference between the volume of the amount delivered and the intended delivery volume. This is the **inaccuracy volume**.
8. Divide the inaccuracy volume by the intended delivery volume and multiply by 100. This is the **accuracy error percentage**. (See Table 14.)
9. If the accuracy error percentage is greater than ± 6%, repeat the test with a new Medication Cassette™ Reservoir. If the pump fails a second time, call Deltec's Customer Service Department.

Example:

Actual Delivery Volume:	19.5 ml
Intended Delivery Volume:	– 20.0 ml
Inaccuracy Volume:	**= -0.5 ml**
Inaccuracy Volume:	-0.5 ml
Intended Delivery Volume:	÷ 20.0 ml
Accuracy Error:	**= -0.025**
	x 100.00
Accuracy Error Percentage:	**= -2.5%**

CADD-Legacy™ PLUS Pump

Power-up Check

- Insert batteries or press (ON/OFF) and observe the LCD during power up. The first screen will display the serial number, model number, and software number with revision level. The second screen will display 32 character blocks. (If "LEC" and four digits appear prior to the pump displaying the 32 character blocks, the pump has experienced an electrical or mechanical fault and should be returned for service.) If no error message is immediately shown, the pump has powered up normally. The pump will then sequentially display all of the programmed values and beep at each screen. After all screens are displayed, successful power up is indicated with six audible beeps and the "STOPPED" screen displayed. Continue with the Lock check.

To Access Biomed Functions Loop

1. Press (LOCK). The current lock level will appear.
2. Press (LOCK) or (ENTER/CLEAR). "CODE 0" will appear.
3. Press (▲) or (▼) until the Biomed function code "165" appears (Lock Code +100). Then press (LOCK) or (ENTER/CLEAR).

Air Detector ON/OFF

1. Press (NEXT) until "Air Detector" appears.
2. Use (▲) or (▼) to select "Off."
3. Press (ENTER/CLEAR) to enter the change.

Changing Delivery Modes

1. Press (NEXT) until "Delivery Mode" appears.
2. Press (▲) or (▼) to select "Continuous".
3. Press (ENTER/CLEAR) to enter the change.

Lock Check

- Attach a 50- or 100-ml Medication Cassette™ Reservoir or a CADD® Administration Set to the pump. The slot on the Cassette Lock button should be aligned with the "Locked" symbol.

Cassette Sensor Check

- Unlock the cassette by inserting a coin into the lock and turning clockwise.
- The pump should issue an audible alarm and the display should read "No Disposable Clamp Tubing".
- Press (STOP/START) or (NEXT) to silence the alarm. Press and hold (ON/OFF) to turn the pump off.

The following three checks (LCD, Motor and Gear Train, and Reservoir Volume Empty Alarm Check) should be performed in the sequence shown.

LCD Check

- With the pump turned off, press (ON/OFF). The second screen that the pump displays will consist of 32 blocks of characters. Examine the LCD to verify that there are no missing dark pixels in the character blocks.

Motor and Gear Train Check

- Program the Reservoir Volume to 2.0.
- Program Biomed to Continuous Mode.

Intended Delivery Volume	Actual Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error Percentage
20 ml	19.5 ml	-0.5 ml	-0.5 ml ÷ 20.0 ml =-0.025	-0.025 x 100 = -2.5%

Table 14. Volumetric percentage calculation

- Attach either a 50- or 100-ml Medication Cassette™ Reservoir or CADD® Administration Set to the pump. Lock the cassette.
- Press and hold (PRIME) until three series of dashes appear. Release (PRIME). Press and hold (PRIME). While priming the pump, listen to the motor for excessive noise or grinding sounds. Count the number of pump activations. The pump should prime ten double activations and then stop. Press (NEXT) to return to the main menu.

Reservoir Volume Empty Alarm Check

- Program the Reservoir Volume to 1.0 ml.
- Press and hold (PRIME) until three series of dashes appear. Release (PRIME). Press and hold (PRIME). The pump should prime ten double activations and then stop. The pump will alarm and display "Reservoir Volume Empty." Press (NEXT).

Starting/Stopping the Pump

- Program the pump with the following values:

Reservoir Volume:	1.0 ml
Rate:	125 ml/hr
Given:	0.0 ml (press (ENTER CLEAR) to clear)

- Program the Air Detector Off.
- Press and hold (STOP START). "Starting" appears followed by three sets of dashes, each accompanied by a beep. A review of the programmed parameters then appears. The main screen should appear with "RUN" in the display.
- To stop the device, press and hold (STOP START). "Stopping" appears followed by three sets of dashes that disappear one at a time, each accompanied by a beep. The main screen should appear with "STOPPED" in the display.

Activation Timing Check

- Reprogram the Reservoir Volume to 1.0 and clear the Given Screen.
- Press and hold (STOP START) until three dashes disappear from the display. The pump should sequentially display all of the programmed values. Start a timer at the first motor activation.
- Count the activations. One activation should occur every three seconds. Approximately twenty-seven seconds and ten activations later, the Reservoir Volume alarm should occur. The display should show "Reservoir Volume Empty."

GIVEN Mode Check

- Press (NEXT) to advance to the Given screen. The display should now show 1.00 ml. (If the above steps have not been followed exactly, a different value may appear.)
- Press the (ENTER CLEAR) key. The display should now show 0.00 ml.

Air Detector Test

This test will verify the function of the air detector. To perform this test, the air detector must be turned on. The previous program from the Activation Timing Check can be used to perform this test.

- Attach an empty Medication Cassette™ Reservoir or CADD® Administration Set to the pump.
- Secure it using the lock button.
- Thread the tubing through the air detector groove.
- Start the pump.
- The pump should respond with a continuous two-tone alarm and the display should read:

  "Air in Line Detected"

- Press (NEXT) or (STOP START) to silence the alarm, and remove the Medication Cassette™ Reservoir or CADD® Administration Set.
- Now attach a Medication Cassette™ Reservoir containing fluid, or a primed CADD® Administration Set to the pump. Make certain there is no air in the fluid path.
- Secure it using the lock button.
- Thread the tubing through the air detector groove.
- Program the Reservoir Volume to 1.0 ml. Start the pump.
- The pump should deliver without an air detection alarm.

Upstream Occlusion Sensor Test

- Verify that the Upstream Occlusion Sensor is turned on. (See page 34, To Access Biomed Functions Loop.)
- Obtain a CADD® Administration Set with bag spike and anti-siphon valve. Also obtain a clamp (slide clamp or hemostat).
- Insert the CADD® Administration Set spike into an appropriate, standard IV bag filled with water. Attach the cassette to the pump. Prime the entire fluid path.
- Program the pump to deliver a continuous maximum rate. Press and hold (STOP START) to start the pump.
- Clamp the tubing halfway between the IV bag and the pump. The pump should alarm within three activations after clamping the tubing.

Occlusion Pressure Range Tests

Occlusion Pressure Range Test I

Description

Pressure is generated by activating the pumping mechanism with an attached filled, clamped Medication Cassette™ Reservoir. The pump is started until the high pressure alarm sounds.

Equipment needed

50- or 100-ml Medication Cassette™ Reservoir containing distilled water

Procedure

1. Insert two AA batteries and wait for the pump to power up.
2. Attach a Medication Cassette™ Reservoir containing water to the pump. Lock the cassette.
3. Prime the Medication Cassette™ Reservoir tubing. The tubing should be filled with fluid to the end of the luer lock connector. The system ***must*** be free from air bubbles for this test.
4. Close the slide clamp on the distal end of the tubing near the female luer of the Medication Cassette™ Reservoir.
5. Program the pump to the following parameters:

Reservoir Volume:	10.0 ml
Continuous Rate:	125.0 ml/hr
Given:	0.0 ml (Press (ENTER CLEAR) to clear)

6. Start the pump. When the pump is running, note when the high pressure alarm is activated.
7. The pump should alarm when the pump delivers between 1 and 2 activations.

Occlusion Pressure Range Test II

Description

An adjustable metered pressure source is connected to the Medication Cassette™ Reservoir tubing. The pressure is slowly increased until the high pressure alarm sounds.

Equipment needed

- Pressure gauge, 40 psi ± 1 psi (2.76 bar ± 0.07 bar)
- Pressure vessel, partially filled with water
- Pressure regulator, 40 psi (2.76 bar ± 0.07 bar)
- 50- or 100-ml Medication Cassette™ Reservoir containing water

CAUTION:

At the completion of the test, the pressure must be reduced to zero before detaching the cassette from the pump; otherwise, the cassette may rupture. Safety glasses should be worn while conducting or observing this test.

Procedure

1. Insert two AA batteries and wait for the pump to power up.
2. Attach a Medication Cassette™ Reservoir to the pump. Lock the cassette.

NOTE:

The pressure from the source must be zero when the cassette is attached.

3. Assemble the apparatus as shown in Figure 13.
4. Connect the Medication Cassette™ Reservoir outlet tube to the metered pressure source.

NOTE:

Do not use a CADD® Extension Set with Anti-siphon Valve.

5. Program the pump for a continuous rate of 125 ml/hr. Press (STOP START).
6. Slowly increase the back pressure, noting when the high pressure alarm is activated.

NOTE:

The pressure may be increased rapidly to 8 psi (0.55 bar), after which the pressure should be increased at 3 psi/min (0.21 bar/min) or less until the alarm sounds.

7. The high pressure alarm should sound within 1.79 (±0.97) bar, or 26 (±14) psi.

Accuracy Testing

Gravimetric Accuracy Testing

Description

A Medication Cassette™ Reservoir is partially filled with water and weighed. The cassette is then attached to the pump and the pump is set to deliver a certain amount of water. The cassette is then removed and weighed again. The amount of water delivered is compared to the amount that the pump should have delivered.

Nominal system accuracy is given in the technical specifications section for the pump. That is, under the test conditions described below, the accuracy of the pump and Medication Casssette™ Reservoir will be nominal with a 90% confidence level. The nominal test conditions are as follows: degassed water at 25 ± 5°C without back pressure.

Equipment needed

- 50- or 100-ml Medication Cassette™ Reservoir
- 50 or 60 ml syringe

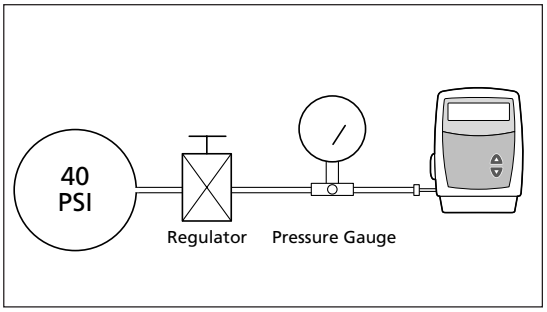

Figure 13. Occlusion test set-up.

- CADD® Extension Set with Anti-siphon Valve
- A balance accurate to 0.1 g
- 40 ml of room temperature water

Procedure

1. Fill the 50- or 60-ml syringe with 40 ml of water. Transfer the water into a Medication Cassette™ Reservoir.
2. Remove any air from the Medication Cassette™ Reservoir by aspirating the air with the syringe. Attach the CADD® Extension Set with Anti-siphon Valve. Prime the tubing so it is filled with fluid to the end of the CADD® Extension Set luer lock connector.
3. Weigh the entire Medication Cassette™ Reservoir/CADD® Extension Set assembly and record the weight. This is the **pre-delivery weight**. (This weight includes the empty Medication Cassette™ Reservoir, CADD® Extension Set, and weight of the water.)
4. Attach the Medication Cassette™ Reservoir to the pump. Program the reservoir volume to 20 ml. Now press (ENTER CLEAR). This value is the **intended delivery volume**. Remove the slide clamp.
5. With the pump in Lock Level 0, program a continuous rate of 125 ml/hr. Start the pump and deliver 20 ml.
6. Again, secure the slide clamp as close as possible to end of the CADD® Extension Set luer lock connector. Remove the Medication Cassette™ Reservoir from the pump and weigh the entire Medication Cassette™ Reservoir/CADD® Extension Set assembly. This is the **post-delivery weight**.
7. Calculate the difference in weight between the pre-delivery weight and the post-delivery weight. This is the **weight of the amount delivered**. (One ml of water at 20°C weighs 1 gram.)
8. Find the difference between the volume of the amount delivered and the intended delivery volume. This is the **inaccuracy volume**.

9. Divide the inaccuracy volume by the intended delivery volume and multiply by 100. This is the **accuracy error percentage**. (See Table 15.)
10. If the accuracy error percentage is greater than ± 6%, repeat the test with a new Medication Cassette™ Reservoir. If the pump fails a second time, call Deltec's Customer Service Department.

Example:

Predelivery Weight:	61.1 g
Postdelivery Weight:	– 41.6 g
Weight of Amount Delivered:	**19.5 g = 19.5 ml**
Volume of Amount Delivered:	19.5 ml
Intended Delivery Volume:	– 20.0 ml
Inaccuracy Volume:	**= -0.5 ml**
Inaccuracy Volume:	-0.5 ml
Intended Delivery Volume:	÷ 20.0 ml
Accuracy Error:	**= -0.025**
	x 100.00
Accuracy Error Percentage:	**= -2.5%**

Volumetric Accuracy Testing

Description:

A predetermined amount of water is delivered into a collection device such as a burette or graduated cylinder. The amount of water delivered is compared to the amount that the pump should have delivered.

Nominal system accuracy is given in the technical specifications section for the pump. That is, under the test conditions described below, the accuracy of the pump and Medication Cassette™ Reservoir will be nominal with a 90% confidence level. The nominal test conditions are as follows: degassed water at 25 ± 5°C without back pressure.

Equipment needed:

- 50- or 100- ml Medication Cassette™ Reservoir
- 50- or 60- ml syringe
- CADD® Extension Set with Anti-siphon Valve
- A fluid collection device such as a burette or a class A 25 ml capacity graduated cylinder
- 40 ml of room temperature water

NOTE:

The test procedure calls for the use of a Medication Cassette™ Reservoir and a CADD® Extension Set with Anti-siphon Valve. An IV bag and CADD Administration Set with integral or add-on anti-siphon valve can be substituted for the Medication Cassette™ Reservoir and CADD® Extension Set with Anti-siphon Valve.

Procedure:

1. Fill the 50- or 60-ml syringe with 40 ml of water. Transfer the water into a Medication Cassette™ Reservoir.
2. Remove any air from the Medication Cassette™ Reservoir by aspirating the air with the syringe. Attach the CADD® Extension Set with Anti-siphon Valve. Prime the tubing so it is filled with fluid to the end of the CADD® Extension Set luer lock connector.
3. Insert the end of the CADD® Extension Set into the fluid collection device.
4. Attach the Medication Cassette™ Reservoir to the pump. Program the Reservoir Volume to 20 ml. This is the **intended delivery volume**. Remove all clamps.

Pre-Delivery Weight	Post-Delivery Weight	Weight of Amount Delivered	Intended Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error Percentage
61.1 g	41.6 g	19.5 g = 19.5 ml	20 ml	-0.5 ml	-0.5 ml ÷ 20.0 ml = -0.025	-0.025 x 100 = -2.5%

Table 15. Gravimetric percentage calculation

5. Program a continuous rate of 125 ml/hr. Start the pump and deliver 20 ml.
6. When delivery is complete, record the volume of fluid delivered. This is the **actual delivery**.
7. Find the difference between the volume of the amount delivered and the intended delivery volume. This is the **inaccuracy volume**.
8. Divide the inaccuracy volume by the intended delivery volume and multiply by 100. This is the **accuracy error percentage**. (See table 16.)
9. If the accuracy error percentage is greater than ± 6%, repeat the test with a new Medication Cassette™ Reservoir. If the pump fails a second time, call Deltec's Customer Service Department.

Example:

Actual Delivery Volume:	19.5 ml
Intended Delivery Volume:	– 20.0 ml
Inaccuracy Volume:	**= -0.5 ml**
Inaccuracy Volume:	-0.5 ml
Intended Delivery Volume:	÷ 20.0 ml
Accuracy Error:	**= -0.025**
	x 100.00
Accuracy Error Percentage:	**= -2.5%**

Intended Delivery Volume	Actual Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error Percentage
20 ml	19.5 ml	-0.5 ml	-0.5 ml ÷ 20.0 ml =-0.025	-0.025 x 100 = -2.5%

Table 16. Volumetric percentage calculation

CADD-Legacy™ Pump Cleaning and Functional Testing Checklist

The following checklist is provided as a guide only to assist in establishing documentation of cleaning and functional testing for the CADD-Legacy™ pump. If service is required, fill out this sheet and return it with the device.

Serial # _____ Reference Number _____ Date _____

(Refer to the Technical Manual procedures.)

I. Cleaning Completed ☐ Yes ☐ No

II. Visual Inspection

- ☐ LCD
- ☐ Occlusion Sensor Seals
- ☐ Valves and Expulsor
- ☐ Cassette Hinge Area
- ☐ Cassette Lock
- ☐ Cassette Sensor
- ☐ Keypad
- ☐ Indicator Light
- ☐ Power Jack
- ☐ Accessory Jack
- ☐ Air Detector
- ☐ Pump Housing
- ☐ Battery Door
- ☐ Battery Compartment

III. Mechanical Inspection

- ☐ Keypad
- ☐ Battery Door
- ☐ Cassette Lock

IV. Functional Inspection

- ☐ Power-up
- ☐ Cassette Lock
- ☐ Cassette Sensor
- ☐ LCD
- ☐ Motor/Gear Train
- ☐ Reservoir Volume Empty Alarm
- ☐ Starting/Stopping
- ☐ Activation Timing
- ☐ Dose Key (PCA)
- ☐ Remote Dose Cord (PCA)
- ☐ Dose Given/Attempted (PCA)
- ☐ MG Given/Given
- ☐ Air Detector

V. Downstream Occlusion Pressure Range Tests

Test 1: Activations Before Alarm _____

Test 2: High Pressure Alarm At _____ psi

VI. Accuracy Testing

Volumetric Accuracy Test

Intended Delivery Volume	Actual Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error Percentage
ml	ml	ml		%

Gravimetric Accuracy Test

Pre-Delivery Weights	Post-Delivery Weight	Amount Delivered	Intended Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error
g	g	ml	ml	ml		%

Deltec

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Medical Systems

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The products described are covered by one or more of the following U.S. Patent Nos. 4,559,038; 4,565,542; 4,650,469; 5,364,242; 5,531,697; 5,538,399; 5,540,561; 5,564,915; 5,567,119; 5,567,136; 5,647,854; 5,695,473; Japanese Patent No. 2034590; European Patent No. 0182502; other patent(s) pending; foreign patents(s) pending.
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